

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**

The screenshot shows the Johns Hopkins Medicine Institutional Review Boards (IRB) website. The header includes the Johns Hopkins Medicine logo and a search bar. The main content area features a navigation bar on the left with links to 'About IRB', 'Forms', 'Guidelines and Policies', 'HIPAA and Research', 'News', 'Resources', and 'Training'. The central text area contains an announcement: 'ANNOUNCEMENT: eIRB 2 will go live on January 27, 2014. For more information...' followed by introductory text about the Institutional Official and the purpose of the IRBs. The right sidebar includes links to 'Login to eIRB', 'Get Training', and 'Contact', as well as a 'What's New' section with a link to 'eIRB 2 Launch More »' and 'Upcoming Training Events More »'.

eIRB Information

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



The screenshot displays the Johns Hopkins Medicine website. At the top, there is a navigation bar with the text "Explore Johns Hopkins Medicine" and a search box. Below this is the Johns Hopkins Medicine logo and a search bar. The main content area is titled "JHM Office of Human Subjects Research - Institutional Review Boards". It features a sidebar with a menu for "About IRB" including links for Overview, Authority, Compliance Monitoring Program, eIRB, FAQs, FederalWide Assurances, Fees, JHM IRBs, and Review Agreements. The main content area has a breadcrumb trail: "Home > JHM Office of Human Subjects Research - Institutional Review Boards > About IRB > Getting Started in eIRB". Below this, the heading "eIRB" is followed by the text "eIRB 2 will go live on January 27, 2014. [For more information...](#)". A list of links is provided: "eIRB FAQs", "eIRB Training", "eIRB Updates", "eIRB Wizards", and "System Requirements". At the bottom center, there is a circular seal for "Full Accreditation" from the "Association for the Accreditation of Human Research Programs, Inc.". On the right side, there is a "Login to eIRB" section with links for "Get Training" and "Contact", and a "Related Links" section with links for "FederalWide Assurances" and "U.S. Dept. Health & Human Services, Office for Human Research Protections".

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?

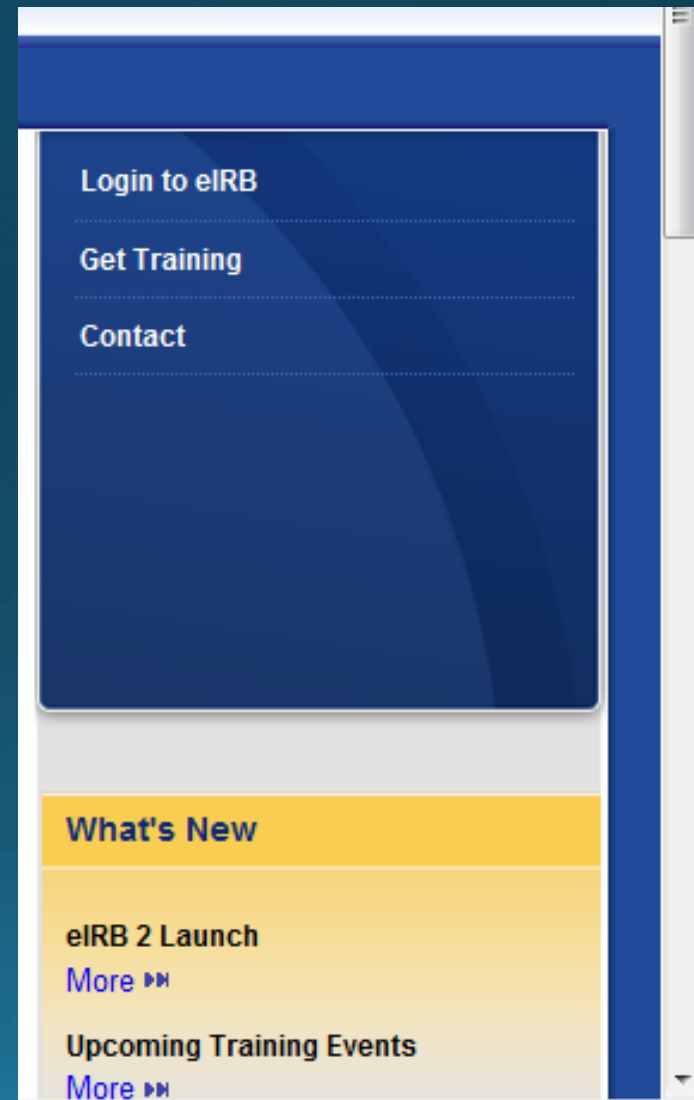
eIRB Wizards are interactive tools designed to help researchers prepare applications for submission to the JHM-IRB for review.

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.



The screenshot shows the Johns Hopkins Enterprise Authentication login interface. At the top left is the 'JOHNS HOPKINS' logo. To its right is a padlock icon and the text 'ENTERPRISE AUTHENTICATION'. Below the logo, the text 'Enter your Login ID and Password' is displayed. There are two input fields: the first contains the text 'jmaddox3' and the second contains a series of dots representing a password. A 'Login' button is positioned below the password field. To the right of the input fields, a paragraph explains the purpose of the system: 'The purpose of Johns Hopkins Enterprise Authentication is to provide a single sign-on functionality for our customers to access many applications with just one login.' Below the login button, there are three links: 'First time JHED User?', 'Forgot Password?', and 'Change Password?'. At the bottom of the form, there are two more links: 'Login Problems?' and 'Frequently Asked Questions'. Below these links, the text reads 'Johns Hopkins Enterprise Authentication - v9.2.0-22' and 'Use of the Johns Hopkins Enterprise Directory (JHED)'.

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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**.



The screenshot shows the Johns Hopkins Enterprise Authentication login interface. At the top left is the "JOHNS HOPKINS" logo. To its right is a padlock icon and the text "ENTERPRISE AUTHENTICATION". Below the logo, there is a prompt "Enter your Login ID and Password". The first input field contains the text "jmaddox3". The second input field is filled with dots, representing a password. A "Login" button is positioned below the password field. To the right of the input fields, there is a paragraph of text: "The purpose of Johns Hopkins Enterprise Authentication is to provide a single sign-on functionality for our customers to access many applications with just one login." Below the login button, there are three links: "First time JHED User?", "Forgot Password?", and "Change Password?". At the bottom of the form, there are two more links: "Login Problems?" and "Frequently Asked Questions". Below these links, there is a version number "Johns Hopkins Enterprise Authentication - v9.2.0-22" and a note "Use of the Johns Hopkins Enterprise Directory (JHED)".

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eIRB Accounts: Non-JHED Users

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



The screenshot shows the Johns Hopkins Enterprise Authentication login interface. At the top left is the "JOHNS HOPKINS" logo. To its right is a padlock icon and the text "ENTERPRISE AUTHENTICATION". Below the logo, the text "Enter your Login ID and Password" is displayed. There are two input fields: the first contains the text "jmaddox3" and the second contains a series of dots representing a password. A "Login" button is positioned below the password field. To the right of the input fields, a paragraph explains the purpose of the authentication system: "The purpose of Johns Hopkins Enterprise Authentication is to provide a single sign-on functionality for our customers to access many applications with just one login." Below the input fields, there are three links: "First time JHED User?", "Forgot Password?", and "Change Password?". At the bottom of the form, there are two more links: "Login Problems?" and "Frequently Asked Questions". Below these links, the text "Johns Hopkins Enterprise Authentication - v9.2.0-22" and "Use of the Johns Hopkins Enterprise Directory (JHED)" is displayed.

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JHMeIRB

eIRB View Approval Letter

eIRB Login

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

JOHNS HOPKINS  ENTERPRISE AUTHENTICATION

Enter your Login ID and Password

The purpose of Johns Hopkins Enterprise Authentication is to provide a single sign-on functionality for our customers to access many applications with just one login.

[First time JHED User?](#) [Forgot Password?](#) [Change Password?](#)

[Login Problems?](#) [Frequently Asked Questions](#)

Johns Hopkins Enterprise Authentication - v9.2.0-22
Use of the Johns Hopkins Enterprise Directory (JHED)

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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.

JOHNS HOPKINS SCHOOL of MEDICINE eIRB2

Reg User 1 Test | My Home | Logoff

eIRB Help Desk eIRB Survey What's New

Page for Reg User 1 Test Components

Account Management
eIRB Training
My IRB Studies

Create New Application
Create...

Welcome to eIRB2

You may view studies from the old eIRB system by following this link: <https://archive.e-irb.jhmi.edu>.

Action Required Researcher Prep In Process **Approved** All My IRB Studies

New Application

Filter by ID [dropdown] Go Clear Advanced

ID	Name	Current State	State Change Date	PI Last Name
IRB00007906	Testing out Send for Review + Record Outcome	Approved	11/21/2013 11:29 AM	Test

8 items page 2 of 8 1 / page

Change In Research

Filter by Name [dropdown] Go Clear Advanced

Name	Study Title	Current State	State Change Date	PI Last Name
Testing Sibley again/does study title get updated if approved?	Testing Sibley again/does study title get updated if approved?	Approved	10/30/2013 1:56 PM	Test

Study Workspace

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

The screenshot displays the eIRB2 interface for a study titled "xxDO NOT USE! Janelle's Test Study for IRB Members". The page includes a navigation menu with "eIRB Help Desk", "eIRB Survey", and "What's New". The study details section shows the following information:

- Title:** xxDO NOT USE! Janelle's Test Study for IRB Members.
- Parent Study Title:** xxDO NOT USE! Janelle's Test Study for IRB Members.
- Parent ID:** IRB00007912
- Number:** CIR00000024
- Principal Investigator:** Janelle Maddox-Regis
- IRB Committee:** IRB-7
- Study Expiration Date:** (blank)
- Review Type:** Convened
- Initial Approval Date:** 11/22/2013
- Date Submitted:** 11/21/2013
- Last Scheduled Review:** 9/6/2014

The "IRB Review Items" table is as follows:

Review Date	Review Type	Outcome	Letter Sent
11/26/2013	Expedited	Approved	View Letter
11/22/2013	Convened	Approved with Administrative Changes	View Letter
11/21/2013	Convened	Tabled	View 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.

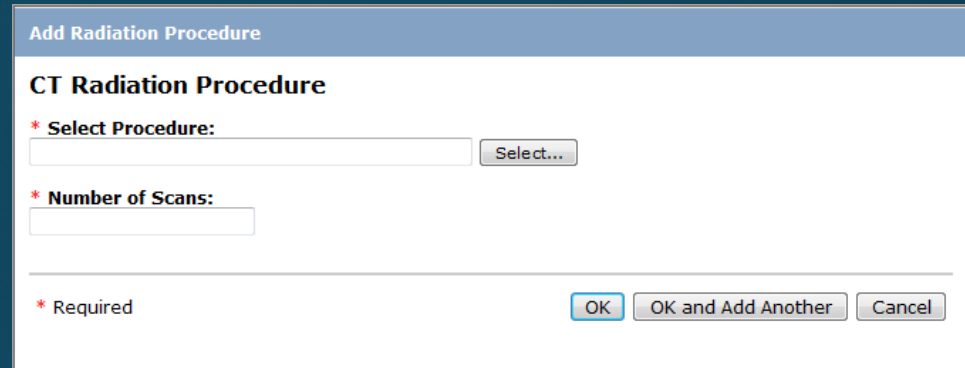
CT Radiology Procedures:

Procedure Type	Scan Amount (rem)
There are no items to display	

CT Radiation Total (rem):

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.



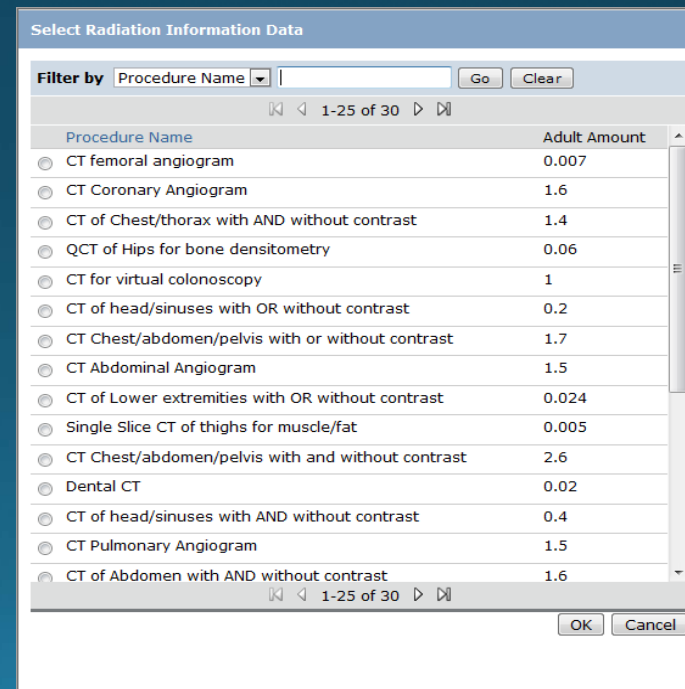
Add Radiation Procedure

CT Radiation Procedure

* **Select Procedure:**

* **Number of Scans:**

* Required



Select Radiation Information Data

Filter by Procedure Name

1-25 of 30

Procedure Name	Adult Amount
<input type="radio"/> CT femoral angiogram	0.007
<input type="radio"/> CT Coronary Angiogram	1.6
<input type="radio"/> CT of Chest/thorax with AND without contrast	1.4
<input type="radio"/> QCT of Hips for bone densitometry	0.06
<input type="radio"/> CT for virtual colonoscopy	1
<input type="radio"/> CT of head/sinuses with OR without contrast	0.2
<input type="radio"/> CT Chest/abdomen/pelvis with or without contrast	1.7
<input type="radio"/> CT Abdominal Angiogram	1.5
<input type="radio"/> CT of Lower extremities with OR without contrast	0.024
<input type="radio"/> Single Slice CT of thighs for muscle/fat	0.005
<input type="radio"/> CT Chest/abdomen/pelvis with and without contrast	2.6
<input type="radio"/> Dental CT	0.02
<input type="radio"/> CT of head/sinuses with AND without contrast	0.4
<input type="radio"/> CT Pulmonary Angiogram	1.5
<input type="radio"/> CT of Abdomen with AND without contrast	1.6

1-25 of 30

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.

Add Radiation Procedure

CT Radiation Procedure

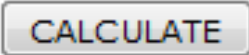
* **Select Procedure:**
CT femoral angiogram

* **Number of Scans:**

* Required

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.

A rectangular button with a light gray background and a thin black border, containing the word "CALCULATE" in black, uppercase, sans-serif font.

3. Total all procedures (rem): 0.014

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.

15. Study Team Members: 

Click **Add** to add new Study Team members. Click **Update** to modify existing Study Team member information.

<input type="button" value="Add"/>								
	Last	First	Degrees	JHED Dept	Primary Affiliation	Role	Consenting Hopkins participants	Agree To Participate
<input type="button" value="Update"/>	Maddox-Regis	Janelle MS	SOM Admin	Clinical Invest Human Subjects	Other - Affiliation Not Listed	Co-Investigator	no	<input type="button" value="Delete"/>

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.)

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.)

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.)

Title	Date Modified	Version	Status
There are no items to display			

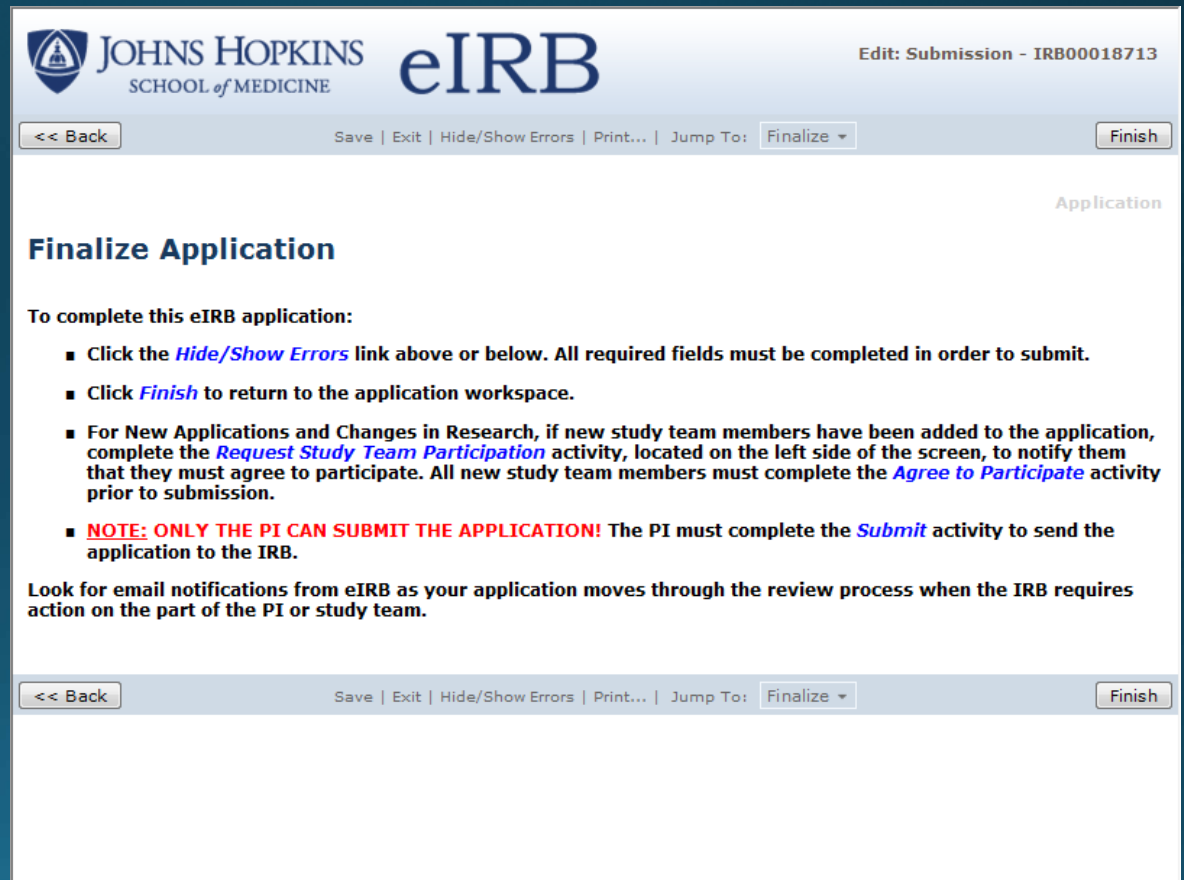
<< Back

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.



The screenshot displays the eIRB application interface for Johns Hopkins School of Medicine. The header includes the university logo and the text 'JOHNS HOPKINS SCHOOL of MEDICINE eIRB'. The current session is identified as 'Edit: Submission - IRB00018713'. A navigation bar at the top contains buttons for '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: Finalize', and 'Finish'. The main content area is titled 'Finalize Application' and contains the following instructions:

To complete this eIRB application:

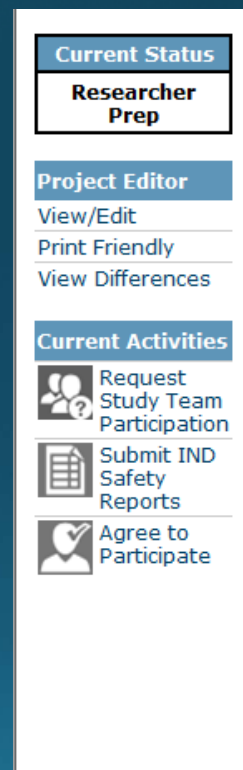
- Click the [Hide/Show Errors](#) link above or below. All required fields must be completed in order to submit.
- Click [Finish](#) to return to the application workspace.
- For New Applications and Changes in Research, if new study team members have been added to the application, complete the [Request Study Team Participation](#) activity, located on the left side of the screen, to notify them that they must agree to participate. All new study team members must complete the [Agree to Participate](#) activity prior to submission.
- **NOTE: ONLY THE PI CAN SUBMIT THE APPLICATION!** The PI must complete the [Submit](#) activity to send the application to the IRB.

Look for email notifications from eIRB as your application moves through the review process when the IRB requires action on the part of the PI or study team.

A second navigation bar at the bottom of the screen is identical to the top one, featuring the same navigation options.

Request Study Team Participation

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

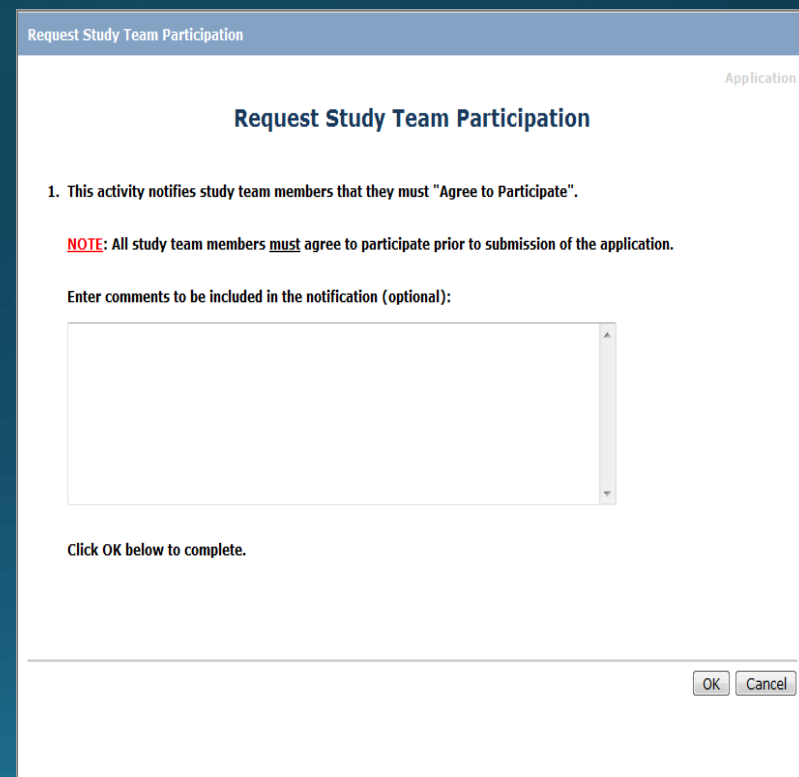


The screenshot shows a vertical sidebar menu with the following sections and items:

- Current Status**
 - Researcher Prep
- Project Editor**
 - View/Edit
 - Print Friendly
 - View Differences
- Current Activities**
 - Request Study Team Participation (with icon of two people and a question mark)
 - Submit IND Safety Reports (with icon of a document)
 - Agree to Participate (with icon of a person and a checkmark)

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 without having received the courtesy email notification.**



The screenshot shows a software application window titled "Request Study Team Participation". The window has a blue header bar with the title and a "Request Study Team Participation" button. The main content area is white and contains the following text:

Application

Request Study Team Participation

1. This activity notifies study team members that they must "Agree to Participate".

NOTE: All study team members must agree to participate prior to submission of the application.

Enter comments to be included in the notification (optional):

[Text input box]

Click OK below to complete.

OK Cancel

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.**

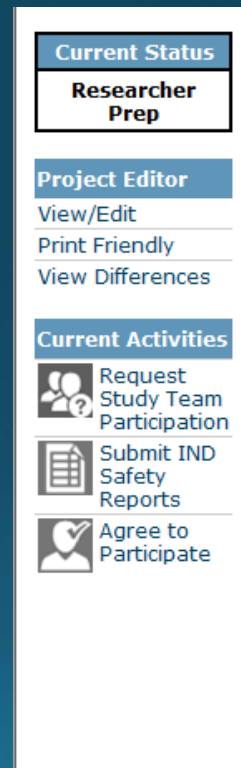
Activity	Author	<input checked="" type="checkbox"/> Activity Date
Changes Updated	Test, Reg User 2	1/17/2014 4:25 PM
Study team member agreed to participate	Test, Reg User 2	1/17/2014 4:25 PM
Study Team participation requested	Test, Reg User 2	1/17/2014 4:24 PM
Changes Updated	Test, Reg User 2	1/17/2014 3:42 PM
Changes Updated	Test, Reg User 2	1/17/2014 3:41 PM
Changes Updated	Test, Reg User 2	1/17/2014 3:40 PM
Changes Updated	Test, Reg User 2	1/17/2014 3:22 PM

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.

The screenshot shows a window titled "Agree to Participate" with a sub-header "Application". The main heading is "Agree to Participate". Below this, it states: "Clicking OK below is the electronic equivalent of a signature." A list of six bullet points follows, detailing the terms and conditions of participation. At the bottom, there are two sections with radio buttons for "Yes" and "No", and a "Clear" link. The first section is "* I agree to the above:" and the second is "* I wish to receive all study related notifications from the IRB:". Below these sections, it says "Click OK below to complete." and at the very bottom, there are "OK" and "Cancel" buttons.

Application

Agree to Participate

Clicking OK below is the electronic equivalent of a signature.

- I have read the protocol and this application.
- I agree to perform the role(s) assigned to me by the PI.
- I certify that I am trained and qualified to perform my role(s) in the study, or will undergo the training that the PI will provide to qualify me to perform my role(s).
- I will familiarize myself with the standard operating procedures for this study before beginning to perform my role(s).
- I will conduct the study procedures in accordance with local, state, and federal laws and regulations, the terms of the JHM IRB approval, and institutional policy.
- Your use of eIRB is governed by all applicable Johns Hopkins policies. eIRB contains information that is confidential and proprietary. Your use of eIRB may be subject to audit. DO NOT submit individually-identifiable information about research participants in eIRB applications. You are responsible for removing all such individually-identifiable patient information from any documents that you upload to eIRB.

* I agree to the above:
 Yes No [Clear](#)

* I wish to receive all study related notifications from the IRB:
 Yes No [Clear](#)

Click OK below to complete.

OK Cancel

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.

The screenshot displays the eIRB Application Workspace for a 'Testing Study for eIRB2'. The interface includes a navigation menu on the left with options like 'Current Status', 'Project Editor', and 'Current Activities'. The main content area shows the application details, including the title 'Testing Study for eIRB2', the number 'IRB00018713', and the principal investigator 'Janelle Maddox-Regis'. A prominent purple message states: '*** APPLICATION WAITING TO BE SUBMITTED ***'. Below this, a note indicates that the application is ready for submission and that the PI should perform the 'Submit' activity. At the bottom, there is a table for 'IRB Review Items' which is currently empty.

Current Status
Researcher Prep

Project Editor
View/Edit
Print Friendly
View Differences

Current Activities
Request Study Team Participation
Submit IND Safety Reports
Agree to Participate

Application Workspace

Title: Testing Study for eIRB2
Number: IRB00018713
Principal Investigator: Janelle Maddox-Regis
IRB Committee:
Review Type:
Date Submitted:
Last Scheduled Review:

***** APPLICATION WAITING TO BE SUBMITTED *****

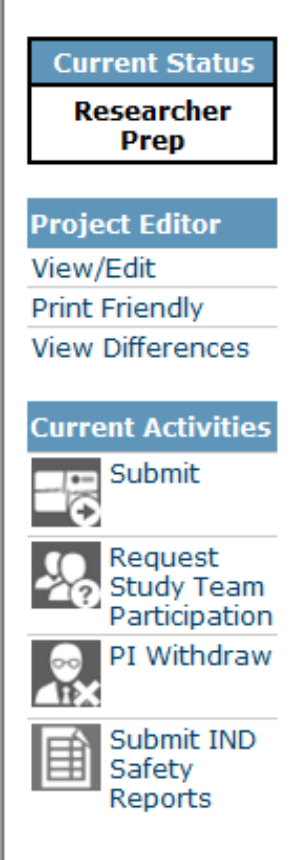
ONLY when application is ready for submission should the **PI** perform the *Submit* activity on the left

IRB Review Items:

Review Date	Review Type	Outcome	Letter Sent
There are no items to display			

Submit the Application

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



The screenshot displays a vertical sidebar menu with the following sections and items:

- Current Status**
 - Researcher Prep
- Project Editor**
 - View/Edit
 - Print Friendly
 - View Differences
- Current Activities**
 - Submit (with a document and arrow icon)
 - Request Study Team Participation (with a group of people icon)
 - PI Withdraw (with a person icon)
 - Submit IND Safety Reports (with a document icon)

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.

Submit

Application

Submit

1. Clicking "OK" below is the electronic equivalent of your signature. By doing so, you agree to the following:

- I have read the protocol and this application.
- All questions on this application are answered truthfully and with appropriate completeness.
- Adequate resources and facilities are available to carry out the proposed research, unless otherwise explained in the Support Section of this eIRB application.
- Investigators will adhere to the current state and federal regulations, local law, and institutional policy governing this research.
- I will ensure that all study personnel have the certification and/or credentialing required by law and by institutional policy to perform their assigned study activities, the appropriate training to conduct the portion of this study in which they are involved, and that they understand the study's standard operating procedures.
- I will ensure that the study personnel understand how to conduct the protocol in accordance with the terms of the JHM IRB approval and guidance.
- Your use of eIRB is governed by all applicable Johns Hopkins policies. eIRB contains information that is confidential and proprietary. Your use of eIRB may be subject to audit. **DO NOT** submit individually-identifiable information about research participants in eIRB applications. You are responsible for removing all such individually-identifiable patient information from any documents that you upload to eIRB.

Upload any additional documents, NOT included in the application, that you wish to include as part of the review (optional):

Click Add to upload document(s):

Add

Title	Description	Modified Date
There are no items to display		

2. Additional Comments (optional):

OK Cancel

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.

JOHNS HOPKINS SCHOOL of MEDICINE eIRB2

Reg User 2 Test | My Home | Logoff

eIRB Help Desk eIRB Survey What's New

Page for Reg User 2 Test Components

Account Management
eIRB Training
My IRB Studies

Create New Application
Create...

Welcome to eIRB2

You may view studies from the old eIRB system by following this link: <https://archive.e-irb.jhmi.edu>.

Action Required Researcher Prep **In Process** Approved All My IRB Studies

New Application

Filter by ID Go Clear Advanced

ID	Name	Current State	State Change Date	PI Last Name
IRB0000120	xxDO NOT USE! Janelle's Test Study for Investigators.	RSS Review - Post IRB	1/17/2014 12:17 PM	Test
IRB00010038	EXEMPT TEST STUDY - JMR	Waiting Outcome	12/4/2013 4:40 PM	Test
IRB00018671	FINAL TESTING - RECORD OUTCOME	Waiting Outcome	1/13/2014 2:43 PM	Test

3 items page 1 of 1 10 / page

Change In Research

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.

The screenshot displays the eIRB2 Investigator Home Page. At the top, the Johns Hopkins School of Medicine logo and 'eIRB2' branding are visible, along with user information 'Reg User 1 Test | My Home | Logoff'. A navigation bar includes 'eIRB Help Desk', 'eIRB Survey', and 'What's New'. The main content area features a 'Welcome to eIRB2' message and a link to view studies from the old eIRB system. A 'Create New Application' button is present. Below, a tabbed interface shows 'Approved' selected, displaying a table of new applications.

ID	Name	Current State	State Change Date	PI Last Name
IRB00007906	Testing out Send for Review + Record Outcome	Approved	11/21/2013 11:29 AM	Test
IRB00007932	#DO NOT USE - JANELLE TESTING (FSAs)	Approved	9/19/2013 12:49 PM	Test
IRB00010026	SUE - Testing Workflow Exempt	Approved	11/14/2013 11:29 AM	Test
IRB00010034	EXPEDITED TEST STUDY - JMR	Approved	10/3/2013 4:59 PM	Test
IRB00010075	Sue CIR Testing	Approved	11/14/2013 11:29 AM	Test

IND Safety Reports Activity

- Locate the Current Activities section.
- Click “Submit IND Safety Reports”.

The screenshot displays the Johns Hopkins eIRB application workspace. The header includes the Johns Hopkins School of Medicine logo and the eIRB title. The user is logged in as 'Reg User 2 Test' with options for 'My Home' and 'Logoff'. The breadcrumb trail shows 'All IRB Studies > Testing Study for eIRB2'. A 'Components' button is visible in the top right.

The left sidebar contains a 'Current Status' section with a 'Researcher Prep' button. Below it is the 'Project Editor' section with links for 'View/Edit', 'Print Friendly', and 'View Differences'. The 'Current Activities' section is highlighted and contains three items: 'Request Study Team Participation', 'Submit IND Safety Reports' (which is the target activity), and 'Agree to Participate'.

The main content area is titled 'Application Workspace' and displays the following information:

- Title:** Testing Study for eIRB2
- Number:** IRB00018713
- Principal Investigator:** Janelle Maddox-Regis
- IRB Committee:**
- Review Type:**
- Date Submitted:**
- Last Scheduled Review:**

A prominent purple message states: ***** APPLICATION WAITING TO BE SUBMITTED *****. Below this, a note reads: **ONLY** when application is ready for submission should the **PI** perform the *Submit* activity on the left.

At the bottom, the 'IRB Review Items' section shows a table with columns for 'Review Date', 'Review Type', 'Outcome', and 'Letter Sent'. The text below the table states: 'There are no items to display'.

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.

The screenshot shows a web application window titled "Submit IND Safety Reports". The window has a blue header bar with the title and a "Submit IND Safety Reports" button. Below the header, the main content area is white and contains the following elements:

- A heading "Submit IND Safety Reports" in blue.
- A numbered instruction: "1. * Check below as applicable (you must choose only one):".
- Two radio button options:
 - IND Safety Report(s) involves changes to consent form(s) or protocol.
 - IND Safety Report(s) involves no changes to consent form(s) or protocol.
- A section titled "Upload IND Safety Report(s) below:".
- A button labeled "Add" to upload documents.
- A table with three columns: "Title", "Description", and "Modified Date". The table is currently empty, with the text "There are no items to display" below it.
- A numbered instruction: "2. Enter IND Safety Report numbers and any other relevant information below. Please note that this information will be included in the IRB acknowledgement email exactly as it is entered.".
- A large, empty text input field for entering report numbers and other information.
- A footer instruction: "Click OK to submit IND Safety Report(s) and receive an email. It will be the only acknowledgement you receive from the IRB.".
- At the bottom right, there are "OK" and "Cancel" buttons.

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.

Submit IND Safety Reports

Application

Submit IND Safety Reports

1. * Check below as applicable (you must choose only one):

IND Safety Report(s) involves changes to consent form(s) or protocol.

IND Safety Report(s) involves no changes to consent form(s) or protocol.

Since the IND Safety Report involves changes to the consent form and/or protocol, you must submit a Change in Research Application and include a copy of the IND Safety Report(s).

Click OK to submit IND Safety Report(s) and receive an email. It will be the only acknowledgement you receive from the IRB.

OK Cancel

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.

JOHNS HOPKINS SCHOOL of MEDICINE eIRB2

Reg User 1 Test | My Home | Logoff

eIRB Help Desk eIRB Survey What's New

Page for Reg User 1 Test Components

Account Management
eIRB Training
My IRB Studies

Create New Application
Create...

Welcome to eIRB2

You may view studies from the old eIRB system by following this link: <https://archive.e-irb.jhmi.edu>.

Action Required Researcher Prep In Process **Approved** All My IRB Studies

New Application

Filter by ID [dropdown] Go Clear Advanced

ID	Name	Current State	State Change Date	PI Last Name
IRB00007906	Testing out Send for Review + Record Outcome	Approved	11/21/2013 11:29 AM	Test
IRB00007932	#DO NOT USE - JANELLE TESTING (FSAs)	Approved	9/19/2013 12:49 PM	Test
IRB00010026	SUE - Testing Workflow Exempt	Approved	11/14/2013 11:29 AM	Test
IRB00010034	EXPEDITED TEST STUDY - JMR	Approved	10/3/2013 4:59 PM	Test
IRB00010075	Sue CIR Testing	Approved	11/14/2013 11:29 AM	Test

Create Change in Research

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

The screenshot displays a software interface with a white background and blue accents. At the top, a blue header bar contains the text "Current Status" in white. Below this, a white box with a black border contains the word "Approved" in bold black text. Underneath, another blue header bar reads "Project Editor" in white. Below this header, three links are listed: "View", "Print Friendly", and "View Differences", each separated by a thin horizontal line. Further down, a blue header bar reads "Current Activities" in white. Below this, there is a small icon of a document with a checklist, followed by the text "Submit IND Safety Reports". At the bottom, a blue header bar reads "Create Further Study Action" in white. Below this header, a button with a grey gradient and rounded corners contains the text "Create..." in black.

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.

JOHNS HOPKINS SCHOOL of MEDICINE eIRB2 New: Submission

<< Back Save | Print.. Continue >>

Further Study Action Selection

* Select the type of Further Study Action you would like to create.

- Change in Research
- Continuing Review
- Protocol Event
- Emergency Use
- Termination Report

<< Back Save | Print.. Continue >>