



IND Safety Reports

- Select “Submit IND Safety Reports” under Current New Application Activities on the Left Navigation Bar.
- Complete question 1.0 “IND Safety Report(s) involve changes to consent form or protocol” or “IND Safety Report involves no changes to consent form or protocol.”
- Upload IND Safety Report(s) into the Submit IND Safety Report window if no changes to consent form or protocol.
- Enter safety report numbers into question 2.0 Comments. These will appear in the History Log and will be included in the IRB 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.

Help Links

- Help links may be found to the right of each question.
- IRB Help including regulations and downloading forms. 
- Information Technology provides step by step technologic instructions. 
- Tutorials are available on the eIRB Home Page <http://irb.jhmi.edu/eIRB/> by clicking “How Do I?” in the Left Navigation Bar.
- eIRB training classes are offered monthly in 320 School of Nursing on the Johns Hopkins Medical Campus and B 402 B Building on the Bayview Medical Campus. Click “Technologic Training” in the Left Navigation Bar of the eIRB Home Page at <http://irb.jhmi.edu/eIRB/> for registration instructions.

Contact Information

jhmeirb@jhmi.edu or 410.955.3008

Technical support for eIRB is available from Monday to Friday, 8:30am to 5:00pm. If you have questions or are experiencing any technical difficulties contact the eIRB Help Desk at jhmeirb@jhmi.edu for assistance.

Review Wizards

- Links to human subjects research, exempt and expedited review wizards may be accessed from the eIRB Home Page, the eIRB Login screen, and from within the application.
- Complete the appropriate wizard to see whether or not a study qualifies for human subjects research, exempt, or expedited, review.
- For those studies qualifying for exempt or expedited review, the review wizard offers a copyable paragraph version of the answers that may be pasted into the application when justification is requested.

IRB/eIRB Internet Addresses

- IRB Website – <http://irb.jhmi.edu/>
- eIRB Home Page – <http://irb.jhmi.edu/eIRB/>
- eIRB Login – <http://e-irb.jhmi.edu>
- eIRB Tutorials - <http://irb.jhmi.edu/eIRB/HowDoI/index.html>

Automatic Notifications

- eIRB automatically notifies the PI and study team members choosing to receive notification each time the application moves from one state to another.
- eIRB automatically notifies the PI of an upcoming expiration at 6 weeks prior to expiration. You can renew your study in eIRB by submitting a Further Study Action – Continuing Review.
- eIRB automatically notifies Study Team Members of an upcoming administrative withdrawal at 60 and 30 days prior to withdrawal. Studies may be administratively withdrawn due to expiration, inactivity, or non-compliance.

Withdraw Application or FSA

Only the Principal Investigator may withdraw an eIRB application or further study action. Select PI Withdraw Study or Request Withdraw under Current Activities on the application/FSA workspace. If you wish to pursue this application/FSA in the future, a new eIRB application or FSA must be created and resubmitted for IRB review.

eIRB Tips & Tricks e-irb.jhmi.edu

<http://irb.jhmi.edu/eIRB/> The eIRB Home Page has links for:

- “How do I?” Tutorials
- Investigator Resources
- Technical Training
- Compliance Training
- Wizards
- eFAQs
- Contact Information
- eIRB Login

eIRB Accounts

To set up an account in eIRB, select “JHED User Self Registration” or “Non JHED User Self Registration” from the eIRB login screen at <http://e-irb.jhmi.edu>.

- **JHED User Self Registration**
If you have forgotten your JHED ID or JHED password **contact JHED directly** at jhed@jhmi.edu or call the JHED IT Support Center at 410-955-HELP.

- **Non JHED User Self Registration**
You will receive an email notification providing you with your login information. Contact jhmeirb@jhmi.edu for assistance.

Compliance Training

There is an institutional requirement for compliance training which must be completed by all study team members before IRB approval may be granted. For more information select “Compliance Training” from the left navigation bar on the eIRB Home Page <http://irb.jhmi.edu/eIRB/>.

Supported Browsers

Your browser must allow cookies, Javascripts, and Java applets. eIRB supports:

- **Microsoft Windows**
Windows (all versions)
Internet Explorer 5.5 or later
Netscape Navigator 7.1x or later
Mozilla 1.5x or later
Firefox 1.0x or later
Opera 7.10 or later
- **Macintosh Computers**
Macintosh OSX or later
Netscape Navigator 7.1x or later
Safari 1.1 or later
Mozilla 1.5x or later

- **Other Recommendations:**
Display capable of at least 1024x768 resolution
High-speed internet connection (128K or higher)


December 2008

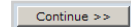
Log into eIRB

- Go to: <http://irb.jhmi.edu/eIRB>
- Click [Click here to Login to eIRB](#)
- Login using your JHED ID and JHED password.
- If you are not Hopkins affiliated, follow the directions on your email account notification.



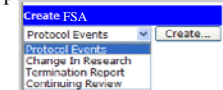
Create a New Study Application

- From your Home Workspace, click 
- Answer the required * fields and click Continue to advance. Completing the General Information page and clicking Continue will create the application and assign the application number.



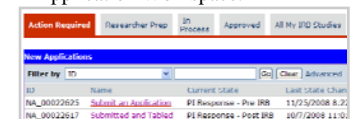
Create a Further Study Action (FSA)

- A FSA can include a continuing review, change in research or protocol events.
- From the Application Workspace select FSA type and click the Create button.



Finding an Application - Tabs

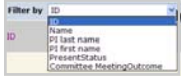
- The Study Team Workspace organizes the workflow using tabs.
- Select the appropriate tab: Action Required, Researcher Prep, In Process, Approved, All My IRB Studies.
- Click the study name to open it to the Application Workspace.



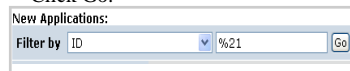
Filter by	ID	Name	Current State	Last State Change
	RA_00022635	Submit an Application	PI Response - Pre IRB	11/25/2008 8:27
	RA_00022637	Submitted and Tabbed	PI Response - Post IRB	10/7/2008 11:01

Finding an Application - Filtering

- Use the “Filter by” drop-down list to select a sort value from the menu.
- Enter the appropriate search value.



- The filter value of NAME allows you to filter by the name of the study, not the name of the PI
- Use the percent sign (%) as a wildcard character. Example: %21 displays all studies containing 21 – NA_0002154, NA_00000021.
- Click Go.



Add Study Team Member Application

- Make sure the study team member has an eIRB account.
- Go to the General Information screen, question 9.0 and click ADD.



Add Study Team Member : Change in Research (Further Study Action)

- Create a Change in Research.
- Select Study Team Member(s) for type of change and click “Continue”.
- Follow the “Click here to go to the Application” link.
- Click ADD on the General Information screen, question 9.0.

Add a Funding or Material Source

- The eIRB system allows unlimited funding and material sources to be listed in the application.
- If you are having trouble locating the funding/material source, email jhmeirb@jhmi.edu to add the funding/material source.

HIPAA Forms

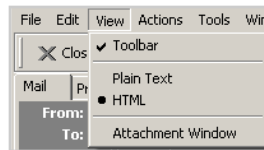
Electronic HIPAA forms do not require signatures. On the signature line **type:** “Submitted electronically through eIRB.”

Documents in eIRB

- Paper copies of grants, Investigator Brochures, sponsor’s protocols, or other documents must be scanned and converted into electronic copies.
- Uploaded documents must be in Adobe Acrobat (.pdf), MS Word (.doc), or HTML (.html) format.
- Do not upload password protected documents.
- Some Macintosh users need to add the three character PC style file-type extensions to Mac file names before uploading into eIRB.

Configuring your Email

- If the notifications you receive from eIRB contain broken links, you may need to reconfigure your email client to display HTML-formatted email.
- In GroupWise select “HTML” from the View drop menu.
- If you use another email client, contact your system administrator for assistance.



Agree to Participate

- Login to eIRB <http://e-irb.jhmi.edu>.
- Select the Researcher Prep tab on the Investigator Home Page.
- Select the study name.
- Select Agree to Participate on the left of the study workspace.
- Click OK. Performing this activity is the equivalent of an electronic signature.

Printer Friendly View

- Provides access to the entire study application and uploaded documents.
- Allows printing the entire application in a printer-friendly version.
- Embedded documents must be opened and printed individually.
- Select Printer Friendly View on the left of the application/FSA workspace.



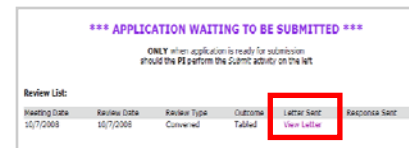
Submit Application/FSA

- PI only: select the “Submit” activity, listed under Current Activities on the application/Further Study Action workspace, after new study team members have completed the Agree to Participate activity.
- The PI does not complete the agree to participate activity. Submitting is the equivalent of an electronic signature.

Review IRB Letters

IRB letters may be found in the Review List on the application/FSA workspace.

- Click the appropriate tab on the Investigator Home Page.
- Scroll down and select the application/FSA. This opens the application/FSA workspace.
- Locate the IRB Letter Sent listed in the Review List.
- Select “View Letter” to open and review the IRB letter.



Respond to IRB Issues

- Complete the IRB requested changes as listed in the IRB letter.
- Select “Respond to Issues” from the Current Activities section of the application/FSA workspace.
- Scroll down and enter a response to each IRB issue.
- Click “OK” to save your response. This does not submit the response.
- Check the response complete box once a response has been entered for each issue, then click “OK” to save your response. This will send an email reminding the PI to submit the response.



Submit Response

- PI only: select the “Submit” activity, listed under Current Activities on the application/Further Study Action workspace, after new study team members have completed the Agree to Participate activity.
- The PI does not complete the agree to participate activity. Submitting is the equivalent of an electronic signature.



Request Extension

- An application may be returned as incomplete before going to an IRB Committee for review. The Principal Investigator has 60 days to resubmit the application. You may seek a 60 day extension of this time limit. Select “Request Extension” under Current Activities on the application/FSA workspace.



- You may also seek an extension for the submission of a response to a posted pending notice, you must submit a formal request in eIRB before the original requested due date. We cannot accept responses beyond the deadline without a JHM-IRB approved extension. Only the Principal Investigator may submit the request. Select “Request Extension” under Current Activities on the application/FSA workspace.

