OHSU Research Integrity Office

101 Guide: eIRB/CoIR/Big Brain
Get to know the basics
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Electronic IRB (eIRB)

Introduction

The purpose of this training is to help familiarize researchers with the basics of the eIRB.

Please feel free to explore the eIRB Playground (http://irbdev/play/) and familiarize yourself with the new features and functionality the eIRB system has to offer.

Login / Register

To register:
Click on Registration to begin and enter Account Registration Form and click the Register button. Within 30 minutes, you will receive an email that contains your temporary password.

To login:
Please visit irb.ohsu.edu/irb and click on the 'Login' link located in the upper right section of the page. You can use the "Forgot Username?" or the "Forgot Password?" links located below the eIRB login page or contact the OHSU Research Integrity Office (ORIO) at (503) 494-7887 or at eirb@ohsu.edu.

Inbox

The eIRB inbox is the page that appears after you log in and contains the items that require an action by study staff and/or submission by the PI. Please check this page on a regular basis and take action on any pending items in a timely manner. If you see a study, modification, continuing review or other action on this page, it is not in the IRB analyst inbox.
**Accessing a Study**

To access a study that is already in the eIRB, you first need to log into the eIRB website.

**My Home**

My Home is the main page of the eIRB. Here you can view studies that have actions you need to perform. Check the modifications, Continuing Reviews and Reportable Events that you have made.

**Studies**

In order to access one of your studies, you need to click on “protocols” tab near the top of the page. A new page will load with all of the studies that you are listed on. To access the study you want to look at, all you need to do is click on that Study’s title.

**Creating New Studies**

Creating a project in the eIRB system is fairly straight forward. After you log into the eIRB main page it will take you to the “My Home” section of the system. On the left hand side you will see a gray tool bar. Inside the tool bar, you will see a button that says “Create New Study”. Clicking on this button will take you to the study set up page. This is also referred to as the Initial Review Questionnaire (IRQ). Work your way through the pages by hitting the “continue” button at the top or bottom of each page. Answer the questions to the best of your ability. If you have any questions about how to answer something in the IRQ, please contact the ORIO office at (503) 494-7887.

**Visual CoIR/RCR**

The visual CoIR/RCR is a tool you can use to confirm the researchers on your staff are fully certified to work on a project. You can find the tool on the left hand side of a projects main page, under “RCR / CoIR Compliance”. It is a visual tool that allows you to simply and quickly look at the color to determine who is compliant with all requirements. Green means they are compliant with the study, Red means they are missing one or more of the requirements for the study.

- **ColR Current**: Confirms user is current in the CoIR management system
- **Confirmed Conflict**: Confirms if a researcher has a conflict of interest with the study.
- **HIPAA**: Indicates the researcher has completed the module in Big Brain.
- **Basic RCR for All**: Indicates the researcher has completed the module in Big Brain.
- **rDNA & Infectious Agents**: Indicates the researcher has completed the module in Big Brain.
Human Subjects Research: Indicates the researcher has completed the module in Big Brain.

FDA Regulated Products: Indicates the researcher has completed the module in Big Brain.

In order to submit a study, all columns must be green or yellow in the Visual CoIR/RCR. Any questions on the status of a researcher’s compliance can be answered by ORIO at 4-7887.

Additional Compliance Approval Status

The Additional Compliance Approval Status tool is located on the left hand toolbar on the study’s main page, in the Quick Views box. To view, click on Additional Approval Compliance Status.

Additional Compliance is a useful tool where you can check on your study’s status with other research compliance Committees in the University (i.e., Biosafety, CoIR, Radiation Safety, OCI, OCTRI, etc.). If your study requires additional compliance review from a committee, this tool will indicate which department you need to contact. This view will also tell you if your project has been approved by the committee.

Tab Exploration

There are 6 tabs on a study’s main page located on the main body, directly below the “Review Category” tool box. In this section we will look at each tab and explain what each one does.

1. Initial Review History

   This tab contains all the information on the history of your study. Stored here are all notes from the Analysts, added documents, sent CRQ notice(s), etc. A note is made so that you, the researcher, are able to view what has occurred in the study.

2. Action Overview

   This tab contains information on actions performed on this study. Here you will find entrees on when the study was approved, a CRQ submission and approval, a Modification submission and approval, along with any Protocol Deviations made to the study. (NOTE: This page does list study activities in chronological order and not by project submission and approval.)

3. Study Documents

   This tab lists all the study documents ever submitted for a study. Use this page to view and download documents in the study.
Official Documents: This “bucket” holds all current IRB approved documents. If you make revisions to any of your documents, you must download them from this tab, make your revisions with the “track changes” function in word and upload the revised, tracked form to your modification or continuing review.

Old Official Documents (Archive): This “bucket” holds all documents that were previously approved by the IRB.

Unofficial Documents: Documents found here are the original study documents that were initially submitted for review when this project was submitted.

4. Modifications

This tab contains Modification requests made or are currently in process. You can view the history of requested changes or continue working on a Modification.

To continue working on a new Modification, simply click the link of the Modification’s name and the main page for that Modification Request will open.

5. Reportable Events

This tab contains a report for the Unanticipated Problems and Protocol Deviations of your study.

For information on reporting Protocol Deviations see the IRB website policy and procedures page at www.ohsu.edu/research/rda/irb/docs/regulatory/PD%20Regulatory%20Sheet.pdf.

For information on reporting Unanticipated Problems, including the PowerPoint presentation on the new policy, please see www.ohsu.edu/xd/research/about/integrity/irb/unanticipated-problems.cfm.

6. Continuing Reviews

The Continuing Reviews tab contains the Continuing Reviews (CRQ) made for your study. You can use this tab to access any CRQ you are currently working on by clicking on the name of the CRQ and following the link. Continuing review is required annually on all studies and due 6-8 weeks prior to the expiration date. You will receive email notifications, however, you should mark your calendars with due dates.
**Requirements for PC and MAC**

The eIRB is a browser based web application. This simply means you need an internet connection and a supported browser to access and interact with the system. All interaction is encrypted via 128bit secure sockets layer (SSL) technology to ensure confidentiality and safety of information contained within the system.

**Supported Browsers for PCs**
- Internet Explorer 5.5 or higher
- Firefox 1.5 or higher
- Netscape 7.1 or higher

**Supported Browsers for the Mac**
- Netscape 7.1 or higher
- Safari 1.2 or higher

**Known Browser Issues**
Mac platform: When a new window is opened to display a document, the user is prompted to download or open with the application of your choice. Either way the new window is orphaned and requires you to manually close it. Opera 9 is not supported.

**Contact Information**

Research Integrity Office  
Phone: 503.494.7887  
Email: irb@ohsu.edu  
Website: www.ohsu.edu/xd/research/about/integrity/irb/index.cfm
Conflict of Interest in Research (CoIR)

The CoIR disclosure form is now found online via the CoIR Management System. It is a separate disclosure from the Big Brain CoI module and must be completed annually; due dates depend on initial submission date.

Effective 8/1/2007, online disclosure system for OHSU & outside investigators as paper forms are no longer available.

Login

Go to www.ohsu.edu/coir. Access to the CoIR online disclosure system is available from any computer with access to the Internet, including off-campus and home computers.

Log in using your Novell (OHSU workstation) user name and password. If you do not know your Novell login, please contact the ITG Helpdesk at 494-2222 or helpdesk@ohsu.edu. If you do not have a Novell login, you must register for an account as a non-OHSU researcher, or sign in using the username and password already created.

Access Form and Submission

The first screen after login is your researcher main page. From here, researchers will be able to see if their CoIR is due and the current status. From this screen you can view and/or edit your contacts and signers. Researchers can review the status of their CoIR disclosure under submission history.

In order to start your disclosure, simply click on the link, that says “Form is now due” under the current year. If you have not recently submitted a disclosure form, your form is open for completion at any time but should only be submitted early if you need to revise your disclosure (e.g., you have a new financial interest to disclose, or a new research project related to your financial interests).
Process

All staff with direct involvement in the design and/or conduct of research (including, but not limited to, the principal investigator, co-investigators, research assistants/coordinators) must complete and submit this form on an annual basis. A revised form should also be submitted if circumstances change during the year and your responses to the questions below have changed.

You may save your form at any time and return to complete it and submit.

If you check yes to any of the questions on the form, additional signatures will be required. Please review the persons listed as 'signers' on the Researcher tab to assure they are correct. Two levels of signature are generally required. Please see www.ohsu.edu/xd/research/about/integrity/coi/upload/Signature-Disclosures.pdf to determine who your appropriate signers should be.

Contact and Signer(s)

Contact is typically department administrators; this person will receive email notifications when CoIR disclosure is due.

Signer is the person who will sign your CoIR Positive disclosure form. To determine who your appropriate signers should be, please visit the CoIR Guide to Signature Requirements at www.ohsu.edu/xd/research/about/integrity/coi/upload/Signature-Disclosures.pdf.

To create a contact/signer, click once on the Create button under Contacts and Signers and follow the steps in the box.

- In the create Contact/Signer window, click once on the list of values icon ．
- Type in the last name of the person, double click their name.
- Chose the type: Contact of Signer
- If signer, choose Sign Level.
- Currently you can only add a contact/signer for OHSU employees, the ability to create this for Non-OHSU researchers is coming soon.
OHSU Conflict of Interest in Research

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Portland, OR 97201-4753

Phone: 503.494.7887
Fax: 503.494.5081
Email: coir@ohsu.edu
Website: www.ohsu.edu/xd/research/about/integrity/coi/system.cfm
Big Brain

Big Brain is a portal for online education at OHSU. Big Brain delivers online education and provides user transcripts and reporting capabilities.

Login/Registration

Go to the Big Brain web site: www.ohsu.edu/integrity/training/bigbrain and click on “go to Big Brain”. If you are an OHSU employee or student, please login using your Novell login and password. If you do not have a Novell login and password, but created an account in Big Brain in the past, enter the login and password you created where it says Novell username and password on the login page. If you are new to Big Brain and will never be assigned a Novell account, please proceed to the registration page by selecting the “register” link on the left where you be asked to create a login and password. After registering, return to the login page and log in.

Registration Type

New to OHSU:
Follow the instructions on the registration page by selecting the appropriate registration type, respectively new OHSU employee or student, employee ID and/or Novell not assigned. As mentioned above, if you will never be assigned a Novell account, please choose the registration type indicating non-Novell. Please also note: if you do not have an employee ID number (for example, students or non-OHSU collaborators) in order for your Big Brain module to feed to the eIRB, you will need to request an employee identification number as an external. Please go to the following link for this information www.ohsu.edu/research/rda/eid_request.php.

Visiting Scientist, non-OHSU student, vendor, or without OHSU login:
Follow the instructions on the registration page click "Register” and select the appropriate affiliation. You will need to provide some additional information about yourself and your affiliation to OHSU and then asked to create a login and password. Once complete, return to the login page and login.
Novell Login and Password
Contact the OHSU ITG Help Desk at 503-494-2222 (6:00a – 6:00p) for assistance with your Novell username and/or password.

Navigating Big Brain

**Taking the course**
1. After logging in to Big Brain you will arrive at the My Courses section. This is your course transcript.
2. Click on the course catalog link located at the top navigation bar.
3. Select the course you desire
4. Click the register button to register for the course
5. Click on the course to launch the web-based training
6. At the completion you will be able to print or e-mail documentation of completion

**Viewing your records**
You can view all courses and their status from the My Courses page. Be sure to click the refresh button to make sure the module information updates.

**RCR Modules**
All study personnel listed must complete the" RCR for All" and "RCR Involving Human Subjects "courses. If your study involves an FDA Drug or an FDA Device, you must also complete the "RCR Involving FDA Regulated Products” course.

**Difference between CoI Outside Activities and CoIR**

Big Brain (CoI) and CoIR Management System are linked. The completion status of each form (if applicable) will be available from your Learner Record in Big Brain.

The CoI module in Big Brain includes an overview of the OHSU CoI requirements. It encompasses four questions dealing with outside activities, executive disclosure, compliance assurance certificate and CoI in Research. This last question asks if you are involved in research. If you answer yes, it will display your current CoI in Research disclosure status, and provide a link if you need to complete the form (note the information will only display for OHSU employees). The CoI module in Big Brain must be completed annually, due July 30th, but is only required for Faculty, those who serve in a Supervisory Role, and those with Fiscal Authority.

Conflict of Interest in Research (CoIR) disclosure is required for those participating in research only and must be completed in a separate online system. For more information, see www.ohsu.edu/xd/about/services/integrity/coi.
Print Certificates

Users can print a certificate either within the course or by following these instructions:

1. Login to Big Brain
2. Click on the My Courses link from the top navigation bar
3. Click on the desired course
4. For completed courses there is a PDF button in the first table, first row to the right of the text, "Status: Completed"
5. Click on the PDF button to open a copy of the certificate
6. Select the print button

Remote Access

The site is accessible from any computer with internet service that meets the system requirements below.

Requirements for PC and MAC

Hardware
- Computer: IBM-compatible PC and Apple Macintosh
- Processor: Pentium or compatible, 300 MHz or better
- Memory: 128 MB RAM minimum
- Display: Monitor (800x600 resolution or higher, 16-bit color)
- Peripherals: Keyboard, Mouse, Network Interface Card, Sound Card (optional), Headphones (optional), Speakers (optional). If you don’t have sound capabilities, you can take a “text only” or "cc" version of a course.
- Connection: Internet or internal network.

Software
- Operating System: Microsoft Windows 98/ME/NT/2000 or Mac OS X (v.10.4.x)
- Web Browser: Microsoft Internet Explorer 5.5 or above (PC) or Safari 2.0.x or above (Mac)
- Browser Plug-ins: Macromedia Flash Player 6
Contact List

**ORIO**
OHSU Research Integrity Office
Phone: 503.494.7887
Fax: 503.494.5081
Email: irb@ohsu.edu
Website: www.ohsu.edu/xd/research/about/integrity/irb/
eIRB Training: www.ohsu.edu/xd/research/about/integrity/irb/eirb_info.cfm

**CoIR**
OHSU Conflict of Interest in Research
Phone: 503.494.7887
Fax: 503.494.5081
Email: coir@ohsu.edu
Website: www.ohsu.edu/xd/research/about/integrity/coi/index.cfm
FAQ: www.ohsu.edu/xd/research/about/integrity/coi/faq.cfm

**Big Brain**
OHSU Integrity Office
Phone: 503.494.8849
Fax: 503.494.8850
Email: oioeduc@ohsu.edu
Website: www.ohsu.edu/integrity/training/bigbrain
FAQ: www.ohsu.edu/integrity/training/bigbrain/faq.cfm

Additional IRB information:

IRB Notes: www.ohsu.edu/xd/about/services/integrity/news/irb/index.cfm
Top Ten Tips for Efficient IRB Review

10. Understand the review process and cover your bases up front.
    Learn the IRB review process (outlined at www.ohsu.edu/xd/research/about/integrity/irb/about_irb_review.cfm) and ensure your project submission includes all relevant information/documents before submitting. If your study involves non-OHSU researchers, arrange and clarify collaborations in advance.

9. Don’t neglect CoIR.
    The eIRB will not allow projects to be submitted or approved unless all researchers involved in a study have completed Conflict of Interest in Research (CoIR) disclosures and Responsible Conduct in Research (RCR) training. In order to prevent delays, encourage your colleagues to respond to CoIR renewal notices promptly.
    Researchers can now submit CoIR disclosures online: www.ohsu.edu/coir

8. Proofread.
    Have you spell-checked? Are your documents consistent? CF’s, Protocols, Lay Protocols, eIRB forms, etc? Common discrepancies between documents include sample size, age range, and study procedures. What’s your study purpose? Ensure your documents provide a clear and consistent rationale for why you are conducting your study.

7. You can never click “OK” too many times.
    The eIRB uses many pop-up windows. Make sure your web browser is not blocking pop-ups. Also be sure to always click “OK” at the bottom of each pop-up window.

6. What’s your status?
    Monitor the status of your project in the eIRB (whether it is a new study, modification request, continuing review, or adverse event report). If the status shows Researcher Preparation, Researcher Revision, or Pre-board Revisions, the project has not been submitted and is not being reviewed. Ask your PI to submit the project.

5. Stack your documents!
    In the eIRB, click “Add or Edit Documents” to upload new or revised documents to a project. Never delete a document – rather, “stack” revised documents over older versions by clicking “edit” next to any currently uploaded docs. Always use the “Track Changes” feature when submitting revised documents. “Clean” versions are not necessary.
4. **Respond in full.**
   If the IRB sends you five questions/requirements for a project and your response only addresses two, we will notice. Incomplete responses only delay reviews further. If you disagree with a change that has been requested, respond to that request with an explanation/justification for your disagreement.

3. **An ounce of prevention is worth a pound of cure.**
   When in doubt, call or email your Managing Analyst to discuss new projects you’re preparing. They can often help you anticipate what sorts of documents you’ll need and what sorts of hang-ups to avoid.

2. **Read the help text!**
   Almost every page in the eIRB includes some help text, often in a grey box on the right side of the screen, strategically placed to provide guidance when and where it is needed.

1. **Contact the ORIO Office** (4-7887, irb@ohsu.edu).
   If you have technical questions about using/navigating the eIRB and the eIRB help text (see above) has let you down, then the ORIO Office is your best resource. The help desk is well equipped to understand what researchers see on their eIRB screens and can help guide researchers about which buttons to click.

   Always reference your eIRB study number.
Details about “Study Status” in the eIRB

In the states listed below, the study or other activity is in the Principal Investigator’s (PI) inbox and requires the PI and/or study staff to complete an action. “The study” refers to the initial submissions and “other activities”, including modification requests (MR), continuing reviews (CR), unanticipated problems (UP), protocol deviations (PD) and terminations. Throughout this document, “The activity” refers to all the above study-related activities.

Reminder: The PI is the only person that can submit a study or other activity.

**Researcher Preparation** – The PI has not submitted the activity and so the IRB (Institutional Review Board), CI (Cancer Institute) or OCTRI (Oregon Clinical and Translational Research Institute) have not received or reviewed any such activity.

**Pre-board Revisions** – The PI has submitted the activity to the IRB, and the IRB has returned it for revisions, often prior to an IRB Chair’s review, and always before going to a full Board meeting.

**Researcher Revision** – The full Board has reviewed an activity and returned it for revision.

**PI Review** – The full board has reviewed the activity and has approved it after having made some minor changes. The chair sends the activity back to the PI for review to either agree or disagree with the minor changes. PI agreement grants IRB approval of the activity; disagreement allows the PI to make further revisions prior to his/her resubmission to the IRB.

**Lapsed** – The study’s IRB approval has expired and the PI must complete an action (termination or CR) in a timely manner. The eIRB system has generated three CR notices by email. When the study expires, the eIRB system sends an email on the day the study expires and another one 10 days later. A CR or termination request must be received within those 20 days post-expiration or the Research Integrity Office will administratively terminate the study, and the department will be charged $500.

In the following states, the IRB has not yet received the study and requires review by these committees prior to being received by the IRB.

**OCTRI Review** – Review to be conducted by OCTRI (Oregon Clinical and Translational Research Institute) conducts the review, which is the initial review, and then sends the study on to the IRB for review prior to giving a complete review and approval.

**CI Review** – Cancer Institute (CI) conducts the review. The IRB does not review the study until the CI review is complete and they have granted approval.

In the following state, the IRB has reviewed and approved the activity and requires additional regulatory review.

**Ancillary Approval Pending** – The IRB has approved the activity and it is awaiting approval from the Radiation Safety Committee, Biosafety Committee, and/or Conflict of Interest in Research.
In the following states, the activity is in the IRB inbox:

**Documents Pending** – The study staff or PI have indicated that a hard copy document has been or will be sent to the IRB. In this state the IRB is **not** reviewing the activity and will not review it until the IRB administrative staff receives the document, and scans and uploads it. Often times study staff checks this in error, so be careful and call (503) 494-7887 if you discover an activity in this state that should not be.

**Pending Docket** – The IRB has reviewed the study but an IRB analyst has not yet claimed it. This only applies to initial submissions.

**Analyst Review** – The activity is in an IRB analyst’s inbox.

**Draft Agenda** – The activity has been placed on a tentative agenda which has not been approved.

**Board Review** – The activity is on an approved agenda. Study staff receive an email after the agenda has been approved informing them of the date of the board meeting.

**IRB Chair Screening** – The activity has been submitted to the IRB Chair for review and/or approval.

**Analyst Revision** – The IRB Chair has rejected the approval for the activity, and is waiting for the analyst to make revisions and send it back for approval.

**Chair Revision Approval** – The IRB analyst has corrected the activity’s approval and has submitted it to the IRB Chair for approval.

**Chair Response Approval** – The activity has been submitted to the Chair for approval. A convened IRB has reviewed the activity, which was approved with minor changes, and the managing analyst completed the revisions. See **PI Review**.

**Chair Confirm Approval** – The activity has been submitted to the Chair for approval after being approved as presented by a convened IRB.

**Triage Review** – The analyst has a question regarding the study and has submitted it to the IRB Chair for assistance.

**Analyst Response Prep** – The Chair has requested changes in an approval memo or review communication after the convened IRB has reviewed the activity. The managing analyst will revise the memo and resubmit it to the IRB Chair for approval.

The following states are when the activity has been approved and no action is being taken.

**Active** – The study is open for subject enrollment.

**Closed to Enrollment** – Subject enrollment is complete. Subjects can still be in follow-up and data analysis is ongoing.

**Terminated** – The study is complete. All subjects have completed all study-related activities, including follow-up. Data analysis is complete and the study has been accepted for publication. If it is a sponsored study, the data has been locked and nothing else is required of the OHSU PI.