
for

Site Administrators

(IRB Staff from Relying Institutions)
This manual is strictly to be used by IRB staff at the Relying Institution and NOT by study teams or the PI. Study teams are not permitted to be Site Administers except in very limited circumstances.

WU Single IRB Contact

If you have questions, concerns, or suggestions regarding the sIRB process please contact Carissa Minder, Manager-Single IRB at carissa.minder@wustl.edu.
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Section 1: Washington University sIRB Review Process

1.1: Reliance Agreements
Relying Institutions will also be asked to sign a Reliance Agreement or an addendum to an existing Master Reliance agreement on a study by study basis. This will be done via email directly with the appropriate contact at the Relying Institution. This process will happen concurrently with the above process.

* One-time process. May already be completed. WU IRB will provide specific instructions on what steps a Relying Institution Site Administrator needs to complete on a study by study basis.
1.2: myIRB Technical Information
The myIRB system works best when using the latest version of Mozilla Firefox or Google Chrome. Internet Explorer and Safari are not recommended.

Section 2: Getting Started in myIRB

2.1 Request a HRPO ID

1. Go to https://myirb.wusm.wustl.edu. You may want to bookmark this page for future use.

2. Click the gray **Request a HRPO ID** button.
3. Select the Site Administrator Role and provide the requested information.

4. You will need to create a Login ID. This will be your **HRPO ID**.

5. When the myIRB Registration page is complete, click **Submit Request**.

6. Within minutes of submitting the form, you should receive a verification email from **myIRB@wusm.wustl.edu** with instructions and a link that you will need to click before your HRPO ID request can proceed.

   This email not a monitored account. Do not reply to the email. Please add **myIRB@wusm.wustl.edu** to your "accepted" email addresses to ensure you can receive emails from myIRB or they may end up in your spam/junk folder. Check your spam/junk mail if the email from myIRB does not arrive within minutes.

7. After verifying your myIRB Registration via email, WU HRPO will be notified of the pending request and will process and approve your **HRPO ID** request.

8. When the request is approved, you’ll receive an email from **myIRB@wusm.wustl.edu** stating that you need to login and update your profile.

9. Go back to **https://myirb.wusm.wustl.edu**

10. Click on **HRPO ID LOGIN**
11. The first time you login, review your profile for correctness and click the **Save and Continue** button. Once this is complete, your myIRB HRPO ID registration process is complete.

### 2.2: Logging in to myIRB

1. Go to [https://myirb.wusm.wustl.edu](https://myirb.wusm.wustl.edu)

2. Click on **HRPO ID Login**
3. If you have forgotten your HRPO ID or password, click the links under the login credentials fields. After you click continue, you will receive an email from myIRB@wusm.wustl.edu with further instructions.
Section 3: Site Registration

3.1: Create the Site Registration

1. Log in using your HRPO ID and password (see Section 2.1).

2. Click on the gray **Create a Site Request** button.

3. You will be taken to the **Site Index** page. Click on the blue **Site Demographics** link to start the form.

4. Complete each question in the form and use the **Save and Continue** buttons to move from page to page.
5. Once all questions are complete, click the **Submit Form** button on the last page.

6. Washington University HRPO staff will review your Site Registration. If there are any questions regarding the information provided, a question will be sent to you via the myIRB system. You will receive an email notification from myIRB@wusm.wustl.edu requesting that you login and address the question.

7. To answer the questions, login using the link from the body of the myIRB@wusm.wustl.edu email. You will be taken to an area known as the **Inbox**. In order to see the question that needs to be addressed, click on the **To Do** file folder icon.
8. Review the questions and the requested changes. Click on the blue **edit answer now** link to go to the question in the Site Index form and change your response.

9. Make the requested changes to the form and click **Index/Save**.

10. Click on the **To Do** file folder icon from the **Inbox** to be taken back to the form with the requested changes. Or, you may click on the file folder icon circled below, to be taken to the questions.
11. When you are back to the requested change form, click the correct radio button and scroll down to find and click the **Return form and my answers** button.

12. Once your Site Registration is approved you will be able to see it under the **Active Sites** tab in myIRB.
3.2: Updating the Site Registration

1. You will need to update the Site Registration if any of the information changes or if you need to add additional Site Administrators. If the Site Administrator has left and you need to replace them, please contact the WU Single IRB Contact for assistance.

2. Login using your myIRB HRPO ID and password.

3. Click on the gray **Site Admin** button on the left hand side of the screen then click on the **Active Sites** tab.

4. Navigate to the section that needs to be updated using the blue links in the white boxes. Once your updates are made, click **Index and Save** and then click the **Submit Site request** link in blue in the middle of the page.

5. Go to the bottom of the next page and all the way to the right and click **Submit Form**.

6. You will receive an email when your changes have been acknowledged.
Section 4: Agreeing to Defer to the WU IRB

4.1: Reviewing the information submitted by your site PI

1. Your site PI should have completed the site application in myIRB (Box 2) and the Site Administrator can now complete the Relying Admin Form (Box 3):

2. Log in to myIRB using your HRPO ID and password that you created (see Section 2.1). [https://myirb.wusm.wustl.edu](https://myirb.wusm.wustl.edu)
3. From your **myInbox**, click on the **IRB ID #** associated with the study you would like to view.

![Image of myIRB interface showing IRB ID numbers and associated study](image)

4. You will automatically be taken to the **Summary** tab page. You can review the application that was submitted to the WU HRPO by clicking the **Details** tab. Depending on your site’s role in the project, you will have access to different information. If your PI is not the lead PI you can review the approved protocol documents under the **Protocol** tab.

![Image of myIRB interface showing Summary tab](image)
4.2: Completing the Relying Admin Form (Agreeing to Defer for a Specific Study)

1. When you have viewed the information and are ready to document your agreement to defer, click on the **myHome** button on the red menu bar to go back to your Inbox.

2. Click on the file folder icon.

3. You will be taken to the electronic **Relying Admin** form. Click on the blue **Relying Admin** link.
4. Answer the questions and click **Continue/Save**. If you do not have the information that you need to answer those questions because the local PI has not provided it, please wait to complete this process until you are able to answer the questions.

There is an **Attachments** page available in the Relying Admin form should you need to attach something. From the Attachments page, click the blue **Click here to ADD or Delete attachment** link and follow the prompts.

Otherwise, review the information on the Relying Admin page and click the **Route Relying Admin form for signature** button.

5. Click the green **SIGN** button. You will be asked to enter in your **HRPO ID** credentials.

6. The study will be sent to the WU sIRB for review.
The site specific consent form process is addressed in Box 2, when the site PI submits the Site Application in myIRB:

The site specific consent form process is as follows:

- **Relying Site Administrator for Relying Site IRB** completes Site Registration in myIRB*
- **Site PI Submits Site Application in myIRB** AND Site PI completes local IRB process
- **Relying Site Administrator completes Relying Admin Form in myIRB** AND completes local IRB Process
- **WU IRB Receives Site Application for Review and Approval**

- **WU IRB Approves Template Consent form from Lead Site**
- **Template Consent form available to sites in myIRB in "Protocol" Tab**
- **Site provides template to local IRB, if needed**
- **Site does NOT need to provide site specific consent form to WU IRB**
Sites do NOT need to provide a site-specific consent form to the WU IRB.

1. As a part of the review of the overall project, the WU IRB reviews and approves a template consent form that contains marked, limited sections for the inclusion of site-specific information.
2. The template consent form is available in myIRB once the site starts drafting their application. It can be retrieved from myIRB and attached to any local application, as required by local policy.
3. The information you provide in the Site Registration form along with the template will be used to create a site-specific consent form for your site.
4. If you have specific areas in the consent form that will need to be changed for your site outside of the marked, limited sections, communicate that information to your local study team and it will be addressed during the review of the site application.
4.4 Accessing Deferred Studies in myIRB

1. As the Site Administrator, you will be able to access the information about your site application myIRB. Click on the **Site Admin** button on the left hand side of the screen after logging in. Then click on the **Active Sites** tab.

2. Click on your Site Name. Then click on the **Protocols** tab.

3. Click on the **IRB ID #** for the study and you will be taken to the study information for that study.
Section 5: Definitions

Reliance Agreement: A written agreement between entities participating in multi-site research. The agreement contains terms that describe what each entity is responsible for in the review, oversight, and conduct of the research including responsibilities related to local requirements, state law, and federal regulations. Previously these were referred to as IAAs or “IRB Authorization Agreements.”

Lead PI: The lead multi-site principal investigator with ultimate responsibility for the conduct and integrity of Research (generally, the initiating principal investigator or funding principal investigator, as applicable). The Lead PI will be responsible for managing the sIRB Project application in myIRB.

Site PI: An investigator(s) responsible for the conduct of the Research at his/her site. The Site PI will be responsible for managing the sIRB Site application for their site in myIRB.

Reviewing IRB: A term used in Reliance Agreements to identify the party to the agreement that acts as the sIRB in providing IRB review for all sites participating in the conduct of the same multi-site protocol.

Relying Site: A term used in Reliance Agreements to identify the party to the agreement that will rely on an IRB outside of its own entity. This is sometimes termed the Relying Institution or Relying Site or Participating Site.

sIRB Project Application: The myIRB application submitted to the WU IRB for approval of the overall project. Often known as a parent application. This application will include approval of the protocol, template consent, questionnaires, and any study wide recruitment materials.

sIRB Site Application: The myIRB application submitted to the WU IRB for approval the site to conduct the research. Often known as a child application. This application will include approval of the site specific consent form and any site specific recruitment or data collection materials.

Site Administrator: The contact person(s) or person’s at the Relying Site IRB or research office who will provide local context information by completing the Site Registration and will sign off on Relying Admin forms in myIRB on a study by study basis. This person it not typically on the study team and must be someone with the authority to agree to defer to the WU IRB on a study by study basis.

Site Registration: A form completed by the Site Administrator in myIRB that provides local context information. This is not a study specific form and only needs to be completed one time.
This form can then be updated as needed. This form must be done before any PI from the site can submit to the WU IRB.

**Relying Admin Form:** A form completed by the Site Administrator on a study by study basis that confirms the study team is appropriately trained and qualified, that all applicable ancillary reviews are complete and that all conflict of interested management plans have been provided. Additionally, is form confirms the Relying Site agrees to defer to the WU IRB for the particular study.