

# *WashU* | **sIRB**

myIRB Single IRB Reference Manual

*for*

SITE PIs and Study Teams

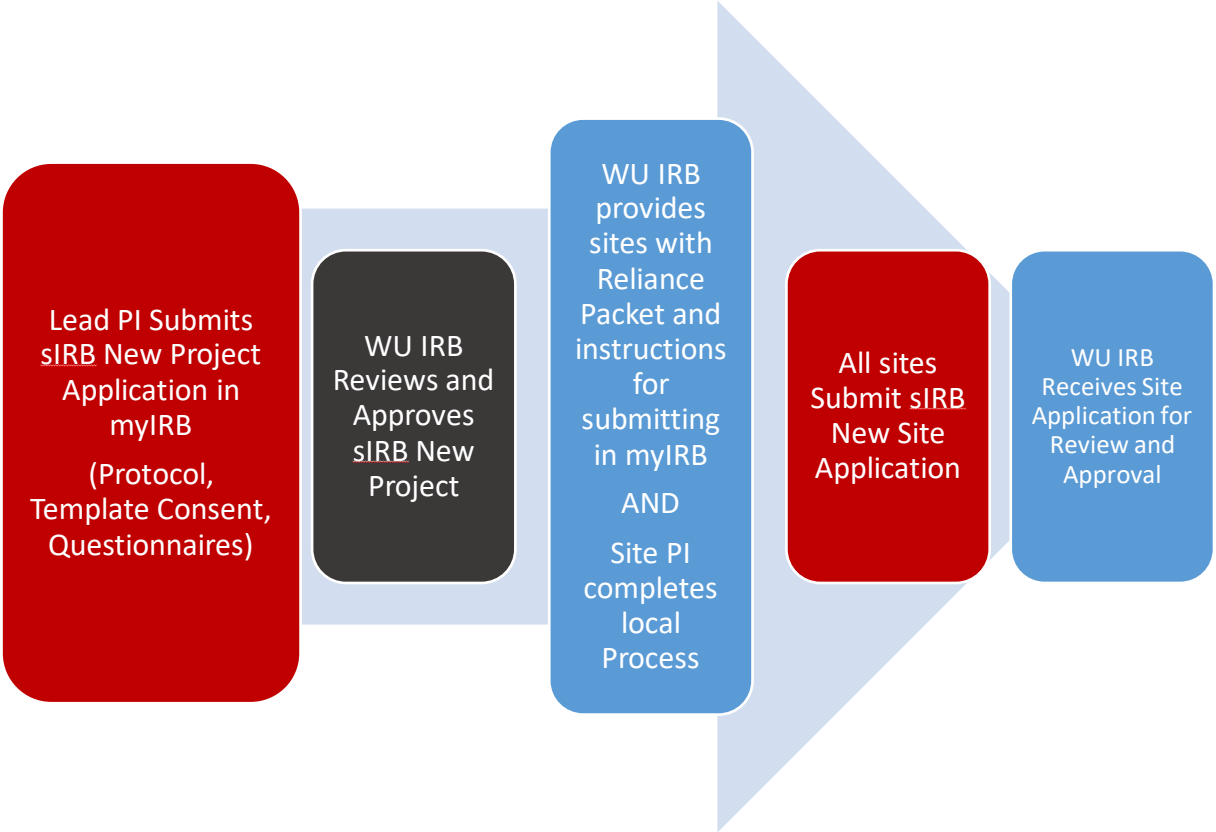
## **WU Single IRB Contact**

If you have questions, express concerns, or suggestions regarding the sIRB process please contact Carissa Minder, at [Carissa.minder@wustl.edu](mailto: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.

## 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.

myIRB

Washington University in St. Louis

Please Sign In | Need Help?

Welcome to myProject and myIRB

The Human Subjects Regulations Have Changed!

The NEW 2018 Common Rule is now in effect.

To learn more about how the new regulations may impact your research, go to the HRPO website at: [2018 Common Rule](#)

If you have difficulty logging in or if you login and do not see all of your studies, please contact HRPO SWAT! for assistance by calling 314.747.6800.

myIRB supports a variety of browsers, e.g. Mozilla FireFox, Chrome, Internet Explorer, Safari, etc. For the best experience, we recommend using the newest version of your preferred browser. Please note that some features will not work fully in older versions of a browser.

WUSTL Key	Login to myIRB using your WUSTL key credentials
BJC-NT User Login	Login to myIRB using your BJC credentials
HRPO ID Login	Login to myIRB using your HRPO provided credentials
<b>Request a HRPO ID</b>	Submit a request to HRPO for a myIRB account
Request Limited Access	Submit a request to HRPO for a limited access myIRB account

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3. Select the **Principal Investigator** or **Research Team** role depending on your role in the study and provide the requested information.

## myIRB Registration

*\*Indicates required field*

*\*Type of access requested.*

- Principal Investigator (PI) - *this role also allows someone to be a member of a research team*
- Research Team - *this role is for individuals other than the PI who will engage in the research*
- IRB Member - *this role should be selected by individuals who have been invited to serve on the IRB*

4. You will need to create a Login ID. This will be your **HRPO ID**.
5. When myIRB Registration is complete, click **Submit Request**.
6. Within minutes of submitting the form, you should receive a verification email from [myIRB@wusm.wustl.edu](mailto:myIRB@wusm.wustl.edu) with instructions and a link that you will need to click before your request can proceed.

This email not a monitored account. Do not reply to the email. Please add [myIRB@wusm.wustl.edu](mailto: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. This usually happens within 1 business day.
8. When the request is approved, you'll receive an email from [myIRB@wusm.wustl.edu](mailto: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**

myIRB Washington University in St. Louis

Please Sign In Need Help?

Welcome to *myProject* and *myIRB*

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If you have difficulty logging in or if you login and do not see all of your studies, please contact HRPO SWAT! for assistance by calling 314.747.6800.

*myIRB supports a variety of browsers, e.g. Mozilla FireFox, Chrome, Internet Explorer, Safari, etc. For the best experience, we recommend using the newest version of your preferred browser. Please note that some features will not work fully in older versions of a browser.*

<input type="button" value="WUSTL Key"/>	Login to myIRB using your WUSTL key credentials
<input type="button" value="BJC-NT User Login"/>	Login to myIRB using your BJC credentials
<input type="button" value="HRPO ID Login"/>	Login to myIRB using your HRPO provided credentials
<input type="button" value="Request a HRPO ID"/>	Submit a request to HRPO for a myIRB account
<input type="button" value="Request Limited Access"/>	Submit a request to HRPO for a limited access myIRB account

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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>
2. Click on **HRPO ID Login**

myIRB Washington University in St. Louis

Please Sign In Need Help?

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<input type="button" value="HRPO ID Login"/>	Login to myIRB using your HRPO provided credentials
<input type="button" value="Request a HRPO ID"/>	Submit a request to HRPO for a myIRB account
<input type="button" value="Request Limited Access"/>	Submit a request to HRPO for a limited access myIRB account

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3. If you have forgotten your password, you can request to change it using the “Forgot HRPO ID password?” link. You will have to provide your Login ID (HRPO ID) and email address for the password reset. After you click continue, you will receive an email from [myIRB@wusm.wustl.edu](mailto:myIRB@wusm.wustl.edu) with further instructions on how to reset your password.

myIRB Washington University in St. Louis

Please Sign In Need Help?

Login using your myIRB HRPO ID credentials

Username:

Password:

Login Forgot HRPO ID username Forgot HRPO ID password

For further assistance contact [HRPO](#).

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## 2.3: Delegates to the PI

1. If you are a PI and would like to have a study team member complete the myIRB application on your behalf, you will need to name them as your delegate in myIRB.

Those that need to access approved materials such as the consent form should be made delegates. The WU IRB does not review or approve the addition of study team members outside of Washington University. Access to the study materials is granted by naming individuals as delegates for the PI rather than study team members.

NOTE: This person must have a HRPO ID to appear in the list. If they do not have a HRPO ID, please refer them to **2.1: Request a HRPO ID**.

- 1) Login using your myIRB HRPO ID and password that you created in Section 2.1.
- 2) Click on the **Personalize** on the red menu bar at the top of the page.
- 3) Click on the gray button that says **Update my delegates**.
- 4) Start typing the last name of the person you would like to act as your delegate in the box. When their name appears, select it.
- 5) Click the **Add Delegate** button.



myIRB > Personalize > User Delegates

Julie Moyer [login as another user](#) | [logout](#) | [delegate login](#)

A principal investigator may name a delegate to act on his/her behalf in myIRB. Once named, the delegate may enter and submit forms for the PI, including all types of application forms and the Serious and/or Unexpected Adverse Experience Form. However, the principal investigator remains responsible for the completeness and accuracy of all submitted forms. If a PI wishes to name a delegate, the IRB encourages the PI to establish documented procedures within his/her research group for reviewing and approving forms prior to their submission.

### User Delegates

To select a name, start typing the name in the following format: **Last, First**. A list will appear to narrow your selection. Type a **space after the comma** and before you start typing the first name. Click Add Delegate when you have selected a user.

[Add Delegate](#)

The following people are currently setup as your delegate. They can log into myIRB and act on your behalf.

Name	Department	Email	
Carissa Minder	Human Research Protection Office	<a href="mailto:minderc@wustm.wustl.edu">minderc@wustm.wustl.edu</a>	<a href="#">remove</a>

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2. If you are a study team member acting as a delegate for a PI to submit an application or address questions you must first log in as the PI.

- 1) Click on the **delegate login** link.

myIRB > Inbox

Julie Moyer [login as another user](#) | [logout](#) | [delegate login](#)

myInbox

Delegate  
IRB Member

### Inbox - To Do

IRB ID #	Entity	To Do	Workflow notes	Days in workflow	Form	IRB Project Title	PI	Current Basket	Previous Basket	From	When
Nothing found to display											

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- 2) Click the **login as [PI Name]** link

myIRB > Personalize > Delegate Login

Delegate Minder [logout](#) | [delegate login](#)

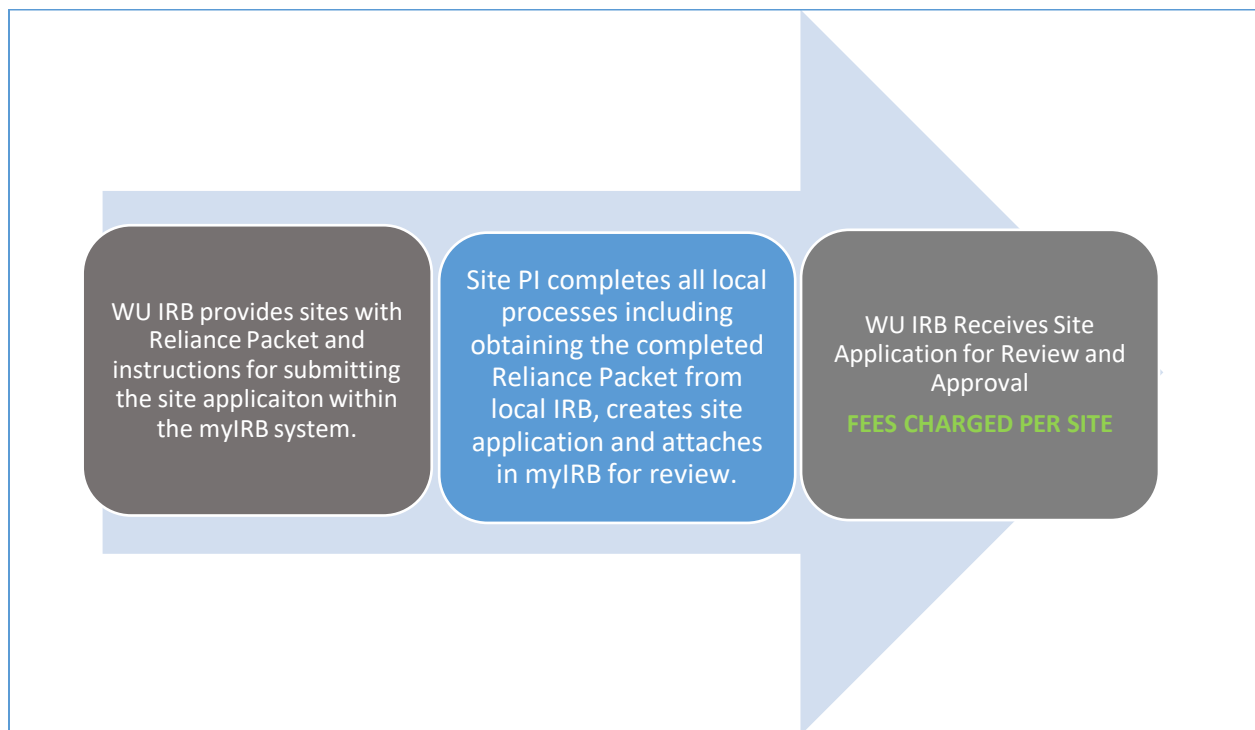
You are listed as the delegate for the following people. Click on the "login" link to the right of the person that you want to login in on behalf of. Once you become that person, you will be taken to their "My myIRB" page and remain signed in as that person until you click on the "logout" link at the top of the page at which time you will be returned to your current login.

Name	ID	Email	
Jonathan Himmel	himmel	<a href="mailto:carissa.minder@wustl.edu">carissa.minder@wustl.edu</a>	<a href="#">login as Jonathan Himmel</a>

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## Section 3: Submitting a Site Application



### 3.1: Site Applications

1. All sites need to submit a **sIRB New Site** application in myIRB to obtain WU sIRB approval to conduct the research at their site. This step will take place after the sIRB New Project is approved by the WU IRB.
2. Sites will also be required to sign either an addendum to an existing reliance agreement or a new reliance agreement. This process will be handled between the two IRBs and the agreements cannot be signed by site PIs.
3. Local sites will be provided a template consent with their Reliance Packet. Local sites should provide the packet to the local IRB per local IRB policies and work with the IRB to obtain the necessary sitespecific information for the consent and local context form.
4. Once the reliance packet is completed and the IRB has signed the required reliance agreement, the packet should be attached in myIRB in the Reliance Documents

category of the myIRB application. The WU IRB cannot move forward with review of your site without ALL documents completed.

5. Local sites do NOT need to add all research team members in myIRB. Team members are tracked at local sites only. Local processes should be followed to ensure the study team is appropriately trained and qualified. Those that need to access approved materials such as the consent form should be made delegates (See Section 2.3 Delegates to a PI).

### 3.2: Submitting the Site Application

1. To submit a Site Application, log in to myIRB and select **Create Project** then choose **sIRB New Site**.

The screenshot shows the myIRB web application interface. At the top, there is a navigation bar with the myIRB logo on the left and the Washington University in St. Louis logo on the right. Below the navigation bar, there is a red header with the text 'myIRB Home Create Project Personalize'. The main content area is divided into three columns: 'Local IRB Review', 'WU sIRB Review', and 'Rely on another IRB'. Under 'Local IRB Review', there are four green buttons: 'New Project', 'Exempt', 'Overall/Concept', and 'Non-Human Decision'. Under 'WU sIRB Review', there are two blue buttons: 'sIRB New Project' and 'sIRB New Site'. Under 'Rely on another IRB', there is one yellow button: 'Request to Rely'. At the bottom, there is a red button labeled 'Cancel'. The 'sIRB New Site' button is circled in red. At the bottom of the page, there is a copyright notice: '© 2018 The University of Iowa, Washington University in St. Louis 5.30.0' and a timestamp: '08/29/18 12:24:00'.

2. You will be prompted to confirm your site PI name and Institution. You will be asked for the IRB ID #.
3. You will then enter the electronic form. To work through the form, start by clicking on the blue **Demographics** link.

4. You can begin answering questions about the project at your site. The form has smart technology so questions will populate or be suppressed based on the responses to other questions. Use the navigation buttons at the top and bottom of the page to go **Back/Save**, **Index/Save**, **Save and Remain**, or **Continue/Save**.

1) Some questions will populate tables. Complete all the information in the table and then hit the blue **Save** link on the right hand side.

2) Some questions will prompt a place to upload attachments. Click on the **Upload File** link follow the instructions on the pop up to attach your document(s).

myIRB > sIRB New Project Form > Source(s) of Support

myProject 2. Source(s) of Support

Type/Source	Grant Title/PI	Status
Federal Agency Maternal & Child Health (DHHS)	Title: PI: Grant Title Julie Moyer	Just in Time

Attachment Name | Comments | Ver | Size | Attached

To edit or version attachments, use the edit link above or go to the attachments page at the end of the application. Instructions for editing or versioning attachments can be found in the attachments table.

[Upload file\(s\)](#)

- If you start a submission and need to log out and come back to it later you can find your draft by logging in to myIRB (or logging in as the PI's delegate, when applicable). Then click on the **myProject** tab and then the **Drafts** tab.

myIRB > Inbox

myProjects

Project Status | **Drafts** | Pending Forms | All Projects

IRB ID #	IRB Title	Form
Unnamed Project		New
Unnamed Project		New
BIO HUD		New
BIO 4,9		New
BIO sfd		New
Unnamed Project		New
Unnamed Project		New
Unnamed Project		HSRD
BIO RTR_TEST		sIRB Project New
BIO Use of Full ICF		New
Unnamed Project		New
Unnamed Project		New
BIO d		New
Unnamed Project		New

- When the application is complete, you will be taken to the **Final Submission Review** page. You will be prompted to complete questions and add missing attachments before the form can be submitted. You will see the name and title of the person who will receive the form for Electronic Signatures for the Assurance Document. When ready, click the **Route form for signatures** button. Once you have selected the Route form for signatures button, the form cannot be edited. The PI will receive an email from

[myIRB@wusm.wustl.edu](mailto:myIRB@wusm.wustl.edu) requesting an electronic signature. The PI can also log in to myIRB and complete this request.

myIRB Washington University in St. Louis

myHome Create Project Personalize

myIRB > sIRB New Project Form > Final Submission Review Delegate Minder as Jonathan Himmel | logout | delegate login

Attachments for the following categories are expected but are not found. Return to the [attachments](#) page to add them. You may proceed to submit without these attachments. However, if HRPO determines the attachments are required, your application may be returned to you without review.

- Listing of Data/Specimen Data Points

Once this form is routed for signatures, you will **not** be able to make any changes unless the form is returned by one of the signers, HRPO or the IRB.

### Electronic Signatures for the Assurance Document

The following will receive electronic signature requests when you submit:

- Principal Investigator - **Jonathan Himmel**

[Research Guide - view Approved Department Signers document](#)

Provide information below if you have discussed this project with a HRPO staff member or IRB Chair prior to submission or if there is other information pertinent to the processing of this form:  
 Note: comments entered in this space can only be accessed by HRPO.

characters remaining: 4000 of 4000  
 (If pasting from copied text, character count in myIRB may not match the character count used by your source document.)

<-- Back/Save      Index/Save      Route form for signatures -->

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- The PI can either click on the link in this email and enter in his or her HRPO ID and password OR can log in to myIRB using his or her HRPO ID and password and click on the file folder icon under the header To Do. The PI will be prompted to enter their HRPO ID and password as a signature.

myIRB Washington University in St. Louis

myHome Create Project Search Reports Dept Reports Scheduling Admin Personalize

myIRB > Inbox ben powell | logout | delegate login

Inbox - To Do				myProjects							
IRB ID #	Entity To Do	Workflow notes	Days in workflow	Form	IRB Project Title	PI	Current Basket	Previous Basket	From	When	
201907026-1021	HRPO ID		0	Regular	sIRB Site CR	BIO DEMO FOR CARISSA	ben powell	PI Signature Requested	Protocol CR Pre Submit	powell 12/12/19 1432	
201810003-1021	HRPO ID		0	Regular	sIRB Site New	BIO Kidney Project	ben powell	Relying Admin Pending	PI Signature Requested	powell 10/11/18 0931	
201809001-1021	HRPO ID		0	Regular	sIRB Site New	BIO In Meeting Test	ben powell	Relying Admin Pending	PI Signature Requested	powell 02/01/19 1428	
201901032-1021	HRPO ID		0	Regular	sIRB Site CR	BIO test for prod	ben powell	Protocol CR Pre Submit	PI Signature Requested	powell 12/10/19 1513	

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- If you are the PI then you will be presented with assurance statements and asked to electronically sign. You will be asked to log in using your **HRPO ID** credentials again to complete this process.

IRB ID #: 201808022  
 Short Title: Manual  
 Form Type: sIRB Site New  
 Person signing: Jonathan Himmel  
 Assurance Type: Assurance Document  
 Person signature type: Principal Investigator  
 Principal Investigator (PI) - As PI, I assure that:

- I am ultimately responsible for the conduct of the study at this site.
- I am qualified to conduct the research as described in the study protocol.
- I have adequate resources, budget, facilities, and numbers of qualified staff to conduct the research at this site as described in the study protocol.
- I agree to comply with all applicable Washington University IRB policies and procedures, and applicable federal, state and local laws.
- The research will only be performed by qualified personnel at this site who have completed human subjects training in compliance with the requirements at this site.
- All persons assisting with the research at this site are adequately informed about the protocol and their research-related duties and functions.
- I will not implement any changes in the approved IRB study protocol, or informed consent process without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of a human participant).
- If unavailable to conduct this research personally, as when on sabbatical leave, I will arrange for another investigator to assume direct responsibility for the study. I will notify the Washington University IRB of such arrangements.
- The research team will only collect information essential to the study. To the greatest extent possible, access to the information will be limited within the research team. If protected health information is used or created, it will not be re-used or disclosed to any other person or entity, except as required by law, research oversight, or those uses outlined in the application.
- If members of the research team access protected health information in order to seek consent/authorization for research, such access is necessary for the research, is solely for that purpose, and the information will not be removed from the covered component.
- Neither I nor any member of the my research team has a financial interest, as defined by my institution's conflict of interest policies, whereby the value of the interest to me or any member of the research team could be influenced by the outcome of the study. Any real or potential conflicts of interest that exist for me or any member of the research team that might affect the relationship with the research participant or the outcome of the research will be disclosed in accordance with institutional policies and appropriately managed, reduced, or eliminated, in cooperation with my institution's conflict of interest review and oversight mechanisms.
- I further assure that the proposed research is not currently being conducted and will not begin until IRB approval has been obtained.

By clicking the Sign button, you are SIGNING this assurance document.  
 You will have to provide your credentials when you click the button.

[Sign](#)

Click on the following link to DENY the signature request:  
[Deny this signature request](#)

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[5.30.0](#)

08/31/18 11:02:54

9. After the form has been signed by the PI, it will be routed to the WU HRPO office for review.

### 3.3: Reviewing Approved Protocol Documents

1. If you need to review the approved protocol level materials, go to the **Project Summary** page by entering in the IRB ID # in the search box and hit **Go** or click on the IRB ID # from your Inbox. Once on the Project Summary page, click on the **Protocol** to access documents.

The screenshot shows the myIRB web application interface. At the top, there is a navigation bar with 'myHome', 'Create Project', and 'Personalize' buttons. The user is logged in as 'ben powell'. The main content area displays the 'Project Summary' for 'Abby's Test'. The summary includes details such as IRB ID # (201810003-1021), Title (Kidney Precision Medicine Project), PI (ben powell), and Status (Pending). There are sections for 'Subjects' and 'FDA' information. A 'Create Form' section lists various forms like 'Modification/Update Form' and 'Continuing Review Form'. At the bottom, there is a 'History' table with columns for Form, Received, Agenda Date, Type, Status, Basket, and Other Review. The 'Protocol' tab is highlighted in the top navigation bar.

Form	Received	Agenda Date	Type	Status	Basket	Other Review
sIRB Site New				Pending	Relying Admin Pending	None

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[5.30.0](#)

10/11/18 11:01:23



2. Click on the little carrots to the left of the dates to open a listing of approved documents associated with that submission.

Summary      Details      Attachments      Research Team      Funding      REFs

▼ **sIRB Project New approved on 2/5/20** (Electronically signed by IRB Chair or Chair Designee: Andrew Godbey, BSN, DDS on 02/05/20 1615)  
[View a printer friendly version of this form](#)

---

**Approval:**

Attachment Name	Category	Version	Date Attached
<a href="#">approval-memo.rtf</a>	Approval Form	1	02/05/20

**Consent/Assent:**

Attachment Name	Category	Version	Date Attached
<a href="#">Consent for testing 1.rtf</a>	Consent & Assent Forms	1	02/05/20

**Separate Written Protocol:**

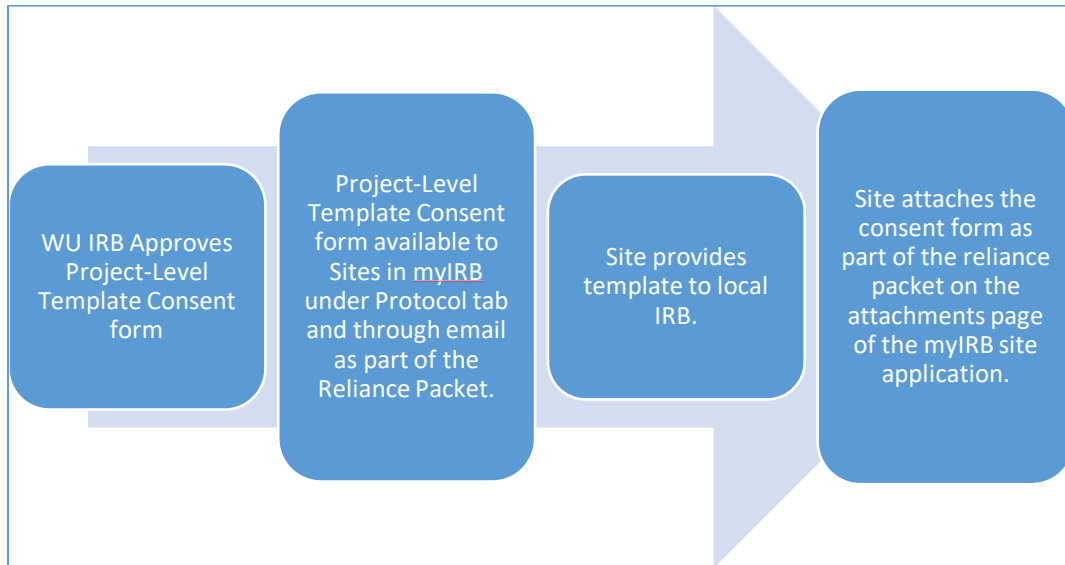
Attachment Name	Category	Version	Date Attached
<a href="#">CHAPTER 1.doc</a>	Intervention: Separate Written Protocol	1	02/05/20

**Subject Data Collection:**  
Nothing found to display

**Recruitment Materials:**  
Nothing found to display

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[5.50.0](#)

### 3.5: Site Consent Forms



1. \*As a part of the review of the overall project, the WU IRB reviews and approves a project-level template consent form that contains marked, limited sections for the inclusion of site-specific information.
2. The project-level 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. The template consent will also be provided to the local site PI through email from the WU HRPO office as part of the Reliance Packet.
3. Sites should provide the template consent to their local IRB for review of site-specific areas. Any changes to the consent form (including changes to highlighted areas), must be completed using the tracked changes feature.
4. If there are specific areas in the consent form outside of the marked, limited sections that will need to be changed for your site, make these changes to the draft consent form during your review using tracked changes in Word and it will be reviewed by the WU IRB to determine if the changes can be accepted.

### 3.6: Answering Questions from the WU sIRB

1. If the WU sIRB has questions about your application, you will be contacted through the myIRB system. The PI and their delegates will receive an email from [myIRB@wusm.wustl.edu](mailto:myIRB@wusm.wustl.edu) notifying them that there are contingencies to address.

If you are the delegate, remember to log in as the PI by using the delegate log in link in the upper right hand corner to see the questions (see Section 2.3).

2. To answer the questions, login using the link in the myIRB 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.

The screenshot shows the myIRB interface. At the top, there's a navigation bar with 'myHome', 'Create Project', and 'Personalize'. Below that, a breadcrumb trail shows 'myIRB > Inbox'. A table titled 'Inbox - To Do' lists items. The first item is circled in red: IRB ID # 201806021, To Do icon, Regular, Form sIRB New, IRB Project Title BIO Manual, PI Jonathan Himmel, Current Basket PI Review, and Previous Basket Admin Prescreen. The footer contains copyright information for 2018 and a timestamp of 08/31/18 09:20:27.

3. You will be directed to the **Workflow** page that will show you what questions or requested changes are being asked of the PI. Click the blue **this link** link to go to the place in the application to address the question or requested changes.

The screenshot shows a workflow page with several sections. At the top, there's a message: 'In the process of reviewing your sIRB New Project Form for the Manual project, additional information is required. All of the questions below will need to be addressed before you return this routing slip to the HRPO office.' Below this, there are instructions: 'The questions do not have to be answered all at once. However, you must save any answers typed in boxes on this page by clicking the SAVE ANSWERS TO CORRESPONDENCE button at the bottom of this page before moving to a different question or a different page.' Another instruction says: 'After review of your response, we may request additional information or revisions. Additional information about the IRB application and review process is available on our web site.' A final instruction states: 'As you move to different pages in myIRB, be sure to SAVE your changes by clicking on any of the buttons at the bottom of each screen. After saving changes, clicking on this icon under the menu bar will quickly return you to this routing slip.' Below these instructions, there's a 'Correspondence From:' section with contact info for Christine Bear. A question is posed: '1: Please attach the data thing. This question requires you to update or add an attachment. Your form has been unlocked and you can go to directly to the attachments page by clicking on this link. Once you have updated your attachment list, please click on the button below to acknowledge that you have made the changes.' Two radio button options are circled in red: 'I have made the requested attachment changes' and 'I have not made the requested attachment changes, see comments'. Below the options is a text input field for comments. At the bottom, there's a 'Save Answers to Correspondence' button and a 'Return form and my answers' button, both circled in red. The footer contains a message: 'Once you have addressed all of the above issues, click the button to the right in order to send this routing slip back to the HRPO office so that your form can continue to be processed.'

Make the changes to the application and click **Index/Save**. Navigate back to the **Workflow** page with the questions or requested changes using the file folder icon in the upper right hand corner of the page under the red menu bar.

From the Workflow page, click on the correct radio button (s). Once you are ready to send the form back to WU sIRB, click the **Return form and my answers** button.

4. The PI and their delegates will receive a notification email from [myIRB@wusm.wustl.edu](mailto:myIRB@wusm.wustl.edu) when the project application has been approved by the WU IRB.

### 3.7: Reviewing Site Approved Materials

1. To review information submitted by and approved for your site, click on **myProjects** from the **myInbox** page. Then click on the **All Projects** tab. You can access study information by clicking the IRB ID #.

myIRB > myInbox

myIRB > myInbox

Inbox - To Do

IRB ID #	To Do	Form	IRB Project Title	PI	Current Basket	Previous Basket
201808021	Regular	sIRB New	BIO Manual	Jonathan Himmel	PI Review	Admin Prescreen

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2. Currently approved attachments, including your site’s consent form, may be located from the **Attachments** tab. Approval memos for your site are attach on the **Approval** tab. DO NOT use the currently approved attachments to modify your consent forms. See **Section 4: sIRB Study Modifications** of this manual about submitting site-specific modifications.

myIRB > Project Summary > Site Project Summary - Abby's Test

ben powell | logout | delegate login

Summary Details Attachments Research Team Funding REFs Approval Protocol

IRB Biomedical  
 IRB ID # 201810003-1021  
 Title Kidney Precision Medicine Project  
 Short Title Kidney Project  
 PI ben powell  
 Status Pending  
 Site Abby's Test

**Create Form**  
[Modification/Update Form](#)  
[Continuing Review Form](#)  
[Modification/Update + Continuing Review Form](#)  
[Reportable Event Form](#)  
[Site Project Close Form](#)

**Subjects**

Subject	Count	FDA	Other
# Approved	10	IND Numbers	See protocol
Minors	N/A	IDE Number	See protocol
Pregnant/Fetus	No	HDE Number	N/A
Cognitively Impaired	No	Non-Significant Risk Device	N/A
Prisoners	No	Emergency Use	N/A

**Review**

Review Item	Status	Other
Next Approval Due By		Certificate of Confidentiality
Closed to Accrual	No	IRB Authorization Agreement
		Unaffiliated Investigator Agreement

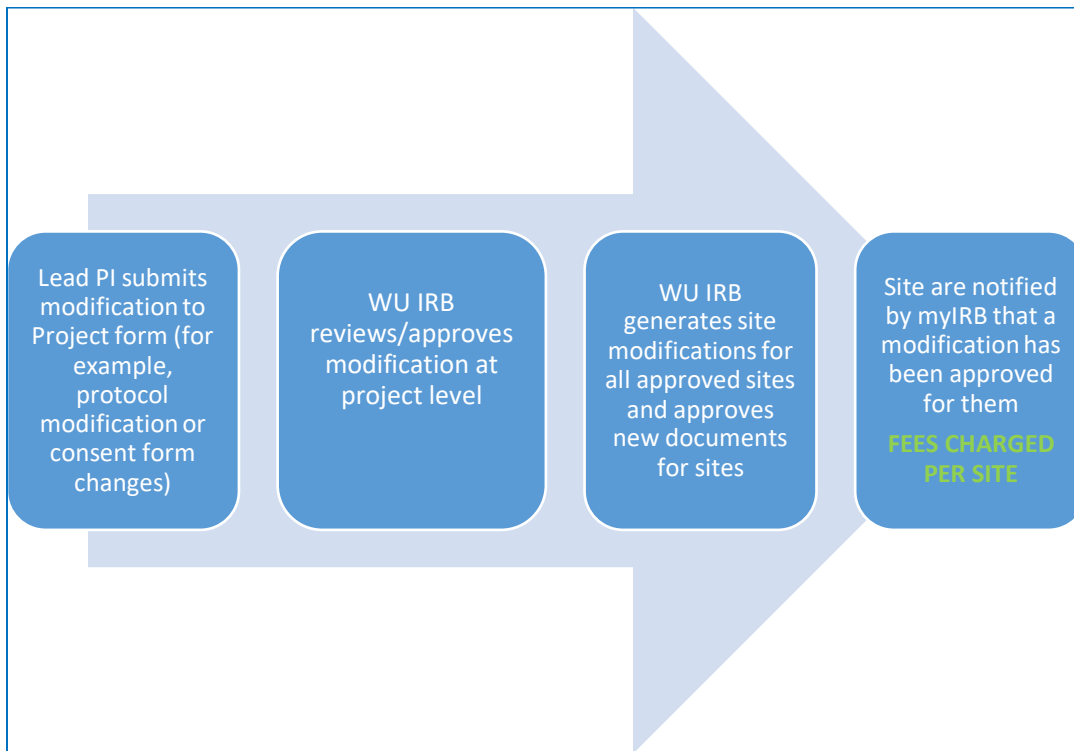
**History**

Form	Received	Agenda Date	Type	Status	Basket	Other Review
<a href="#">sIRB_Site_New</a>				Pending	Relying Admin Pending	None

History Filter: Project Form

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## Section 4: sIRB Study Modifications



1. Changes that need to be made to the protocol or other study-wide information should be submitted as a modification to the project application by the lead site. You will need to contact the Lead Site PI to make these types of changes if they are needed.
2. Once the modification of the project application is approved, modifications will be automatically generated for each site and approved. Sites will be notified of the modifications and will need to log in to myIRB to obtain any updated documents.
3. Sites are permitted to make limited site-specific modifications on their own such as updates to their planned recruitment methods or contact information in the consent form.

## 4.1: Submitting a Modification

1. Locate your study by logging in to myIRB and clicking on **myProjects**.

The screenshot shows the myIRB interface. At the top right, the Washington University in St. Louis logo is visible. Below the navigation bar, there is a search box and a 'Go' button. The main content area is titled 'Inbox - To Do' and contains a table with the following data:

IRB ID #	To Do	Form	IRB Project Title	PI	Current Basket	Previous Basket
201808021	Regular	sIRB New	BIO Manual	Jonathan Himmel	PI Review	Admin Prescreen

The 'myProjects' link in the top right corner of the main content area is circled in red.

2. Click on the **All Projects** and then click on the blue link with the IRB ID #. This will take you to the **Project Summary** page.
3. Click on **Modification/ Update Form** on the Summary page.

The screenshot shows the myIRB interface for a project summary. The project title is 'Abby's Test'. The 'Create Form' link is circled in red. The page is divided into several sections:

- Summary:** Biomedical, IRB ID # 201810003-1021, Title Kidney Precision Medicine Project, Short Title Kidney Project, PI ben powell, Status Pending, Site Abby's Test.
- Subjects:** # Approved 10, Minors N/A, Pregnant/Fetus No, Cognitively Impaired No, Prisoners No.
- Review:** Next Approval Due By, Closed to Accrual No.
- FDA:** IND Numbers See protocol, IDE Number See protocol, HDE Number N/A, Non-Significant Risk Device N/A, Emergency Use N/A.
- Other:** Certificate of Confidentiality See protocol, IRB Authorization Agreement N/A, Unaffiliated Investigator Agreement N/A.

The 'History' section shows a table with the following data:

Form	Received	Agenda Date	Type	Status	Basket	Other Review
sIRB_Site_New				Pending	Relying Admin Pending	None

- A copy of your currently approved application is created. Use the links to navigate to the appropriate sections of the application and make the required updates.

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[.49.0](#)

- To update attachments, navigate to the **Attachments** page by clicking the blue **IRB Application** link the middle of the page shown above and then click the blue **Attachments** button.

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[5.39.0](#)

05/23/19 03:35:25



- When you get to the Attachments page, **DO NOT CLICK EDIT!** Click on the blue link with the name of the document you want to edit first and save a copy to your computer. Make the appropriate edits using **TRACKED CHANGES**.
- Once you have the edited document, click the blue **EDIT** link next to that document.

myIRB > sIRB Project Modification Form > Consent Documents & Other Attachments

Jonathan Himmel | [logout](#) | [delegate login](#)

[← Back/Save](#) [Index/Save](#) [Save and Remain](#) [Continue/Save →](#) [102]

**Important**

Your answers in this form determine which attachments are expected and the contents of any consent document template that is generated for you. If you haven't answered all required questions in this form, the expected attachments list may be incorrect and the text in any consent templates you generate may not meet the requirements for the study.

Also, note that if you make any changes to the form after you have attached any documents, your attachments may no longer apply or be correct.

▶ About Attachments

Consent/Assent Documents and Information Sheets for Exempt Studies\*

▶ Upload Tips for the Consent/Assent Document Category

\*Note: if you are submitting an EXEMPT study, you may attach the Exempt Information Sheet from the list below instead of an Informed Consent Document. If the IRB determines that a full Consent Document is required, you will be asked to provide it after initial review of your study.

Informed consent (for teenagers and older) !

[Select Template](#)

- [Instructions for Writing a Consent](#)
- [Suggested Language for Biomedical Research](#)
- [Suggested Language for Behavioral Research](#)
- [Instructions for Signature Lines](#)
- [Radiation Risk Consent Language Flowchart](#)

! [Lay language terms for consents](#)

Other Supporting Documents

▶ Tips for stamped recruitment materials

Attachment Name	Category	Ver	Size	Attached
<a href="#">WU Constantino Appendix J.1.a Invitation Call Script - POP source selection SEED 3 MO SEED 09.12.18.rtf</a>	Consent & Assent Forms	1	1 712 k E	10/11/18 <a href="#">EDIT</a>

[Click here to ADD or DELETE attachment\(s\)](#)

Attachment Name	Category	Ver	Size	Attached
<a href="#">blank-template.rtf</a>	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	33 k E	10/11/18 <a href="#">EDIT</a>

[Generate Blank Template](#)

- Scroll down to the bottom of the page, Browse and find the document and click the **Upload Attachment** button.

<a href="#">MU Kanne Appendix J.1.a Invitation Call Script - POP source selection SEED 3 MO SEED 09.12.18.rtf</a>	Separate Written Protocol				10/11/18 <a href="#">delete</a>   <a href="#">EDIT</a>
<a href="#">COVET STUDY PROTOCOL AMENDMENT 2_08Dec2017.pdf</a>	Subject Data Collection Instruments	1	688 k		10/11/18 <a href="#">delete</a>   <a href="#">EDIT</a>
<a href="#">TC SEED Social Story 09.12.18.docx</a>	Curriculum Vitae of Principal Investigator	1	503 k		10/11/18 <a href="#">delete</a>   <a href="#">EDIT</a>
<a href="#">assurance-document.rtf</a>	Listing of Data/Specimen Data Points	1	7 M		10/11/18 <a href="#">delete</a>   <a href="#">EDIT</a>

**Edit Electronic Attachment**

**Step 1:** Click on the link below and save the document to your local disk drive. Remember to give your documents a short, study-specific name.

Attachment: [WU Constantino Appendix J.1.a Invitation Call Script - POP source selection SEED 3 MO SEED 09.12.18.rtf](#)

Category: Consent & Assent Forms

Version: 1

**Step 2:** Make changes to the document that you saved in Step 1. If modifying an already IRB-approved document, please turn on "track changes" in your word processor.

**Step 3:** Once you have saved your changes, indicate the document name below and press the "Upload Attachment" button. The edited document will appear in the list of attachments above.

Attachment Name:  No file selected. **select one file** (max size: 1000MB)

Comments:

characters remaining: 4000 of 4000  
(if pasting from copied text, character count in myIRB may not match the character count used by your source document.)

[Upload Attachment](#) [click here](#) to add a new attachment.

[Return to the sIRB Project Modification Form](#)

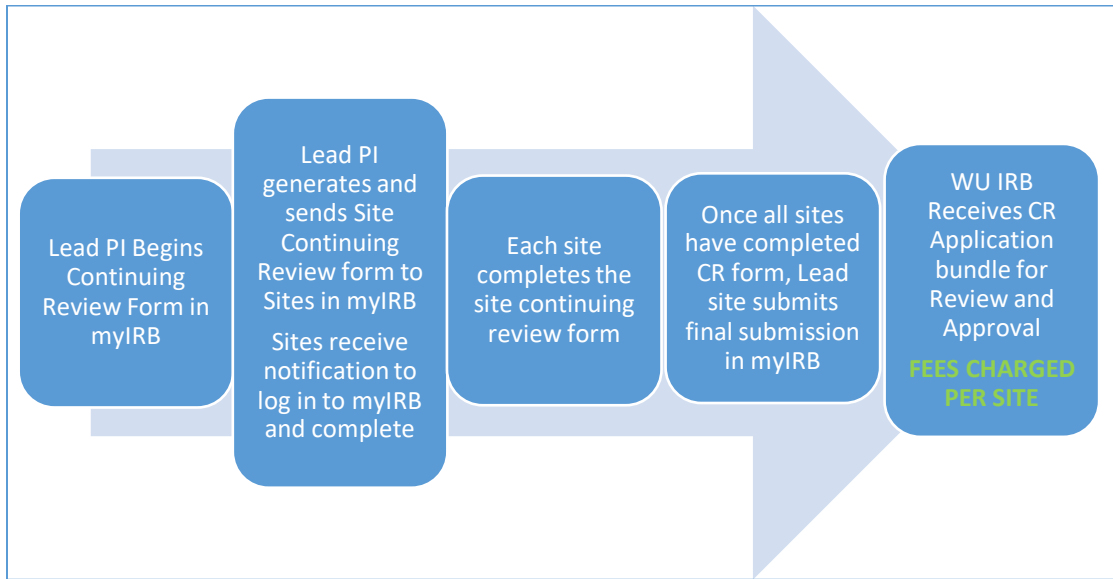
© 2019 The University of Iowa, Washington University in St. Louis 05/23/19 03:40:46

9. Once you have completed your changes, click on the Review and Submit button.

The screenshot shows the myIRB web application interface for a 'Kidney Project'. The page header includes the myIRB logo, navigation tabs (myHome, Create Project, Search, Reports, Dept Reports, Scheduling, Admin, Personalize), a search bar with '201810003', and the HRPO Web Site link. The user is identified as Jonathan Himmel. The project title is 'Kidney Project' with PI: Jonathan Himmel. A 'Change Form' dropdown menu is visible, set to 'Modification/Update Only'. The main content area is titled 'Modification Index' and contains a progress bar with steps 1 through 6. Step 3, 'Performance Sites', is the current step. Below the progress bar are three myIRB cards: '1. Protocol', '2. Participants', and '3. Performance Sites'. The 'Review & Submit' button is circled in red, and a red arrow points to the right. The footer includes copyright information for 2019 and the date 05/23/19 03:35:25.

10. The PI and their delegates will receive a notification email from [myIRB@wusm.wustl.edu](mailto:myIRB@wusm.wustl.edu) when the modification has been approved by the WU IRB.

## Section 5: sIRB Continuing Review Submission



### 5.1: Submitting a Continuing Review

Do NOT start a continuing review form for your site until the Lead PI has started the Project CR.

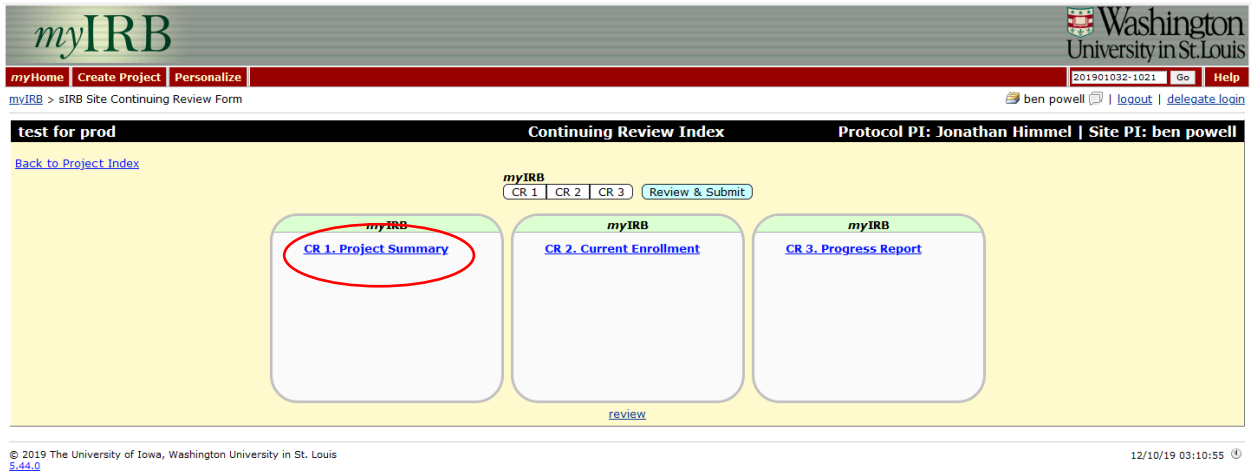
1. You will receive an email from myIRB telling you that you need to log in and complete your Site Continuing Review form.
2. Go to the PI's Inbox and click on the file folder icon under the **To Do** heading.

The screenshot shows the myIRB web application interface. The top navigation bar includes 'myHome', 'Create Project', and 'Personalize'. The user is logged in as 'ben powell'. The main content area displays the 'Inbox - To Do' section, which contains a table of tasks. A red circle highlights the 'To Do' column header. The table lists three tasks, each with an IRB ID, a 'To Do' icon, a form type, a project title, a PI name, a current basket status, and a previous basket status.

IRB ID #	To Do	Form	IRB Project Title	PI	Current Basket	Previous Basket
<a href="#">201810003-102</a>		sIRB Site New	BIO Kidney Project	ben powell	Relying Admin Pending	PI Signature Requested
<a href="#">201809001-102</a>		sIRB Site New	BIO In Meeting Test	ben powell	Relying Admin Pending	PI Signature Requested
<a href="#">201901032-102</a>		sIRB Site CR	BIO test for prod	ben powell	Protocol CR Pre Submit	

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S.44.0  
12/10/19 03:07:18

3. Click on **CR.1 Project Summary** to open the site-specific CR questions and click **Continue/ Save** to save your responses and move forward with the site specific CR form. You do not need to attach any documents.



4. When complete, click the **Route form for signatures** button so the PI can sign the form. If this form is routed for signatures by a delegate, the PI will need to sign in to myIRB, click the file folder icon under **To Do** to access the page where they sign the form. Alternatively, the PI may click on the link in the myIRB email notifying them that their signature is required.
5. Once all sites have completed their information, all the forms will be reviewed together and if the CR is approved, you will receive an email from myIRB letting you know this information.

**NOTE: IF YOU DO NOT COMPLETE YOUR SITE'S PORTION OF THE CR, THE FORM MAY BE SUBMITTED WITHOUT YOUR INFORMATION. SHOULD THIS HAPPEN, YOUR SITE WILL BE CLOSED AND WILL HAVE TO STOP CONDUCTING RESEARCH.**

## Section 6: sIRB Reportable Events

Sites have the ability to, and are required to, submit any events meeting the definition of a Reportable Event to the WU IRB. The WU IRB Reporting Requirements must be followed, and sites may also have reporting requirements they must follow locally. Please see the [HRPO website](#) for information about the WU IRB reporting requirements.

### 6.1: Submitting a Reportable Event

1. After logging in to myIRB, navigate to the **myProjects** tab and then the **All Projects** tab. Click on the IRB ID # for the study.
2. From the Create Form section, click on **Reportable Event Form**.

The screenshot shows the myIRB interface for a project summary. The 'Create Form' section is highlighted, and the 'Reportable Event Form' link is circled in red. The interface includes navigation tabs, a project details table, and a history table.

IRB	Biomedical	Create Form
IRB ID #	201907026	<a href="#">Modification/Update Form</a>
Title	STUDY FOR DEMONSTRATIONS	<a href="#">Continuing Review Form</a>
Short Title	DEMO FOR CARISSA	<a href="#">Reportable Event Form</a>
PI	ben powell	<a href="#">Project Close Form</a>
Status	Open	
Site	Abby's Test (1021)	

Subjects	FDA
# Approved	IND Numbers
Minors	IDE Number
Pregnant/Fetus	HDE Number
Cognitively Impaired	Non-Significant Risk Device
Prisoners	Emergency Use

Review	Other
Next Approval Due By	Certificate of Confidentiality
Closed to Accrual	IRB Authorization Agreement
	Unaffiliated Investigator Agreement

History	Received	Agenda Date	Type	Status	Basket	Other Review
sIRB Project New	07/19/19		Exp	Approved on 07/19/19		None

3. Provide the requested information and use the **Continue/Save** buttons to move through the sections.
4. Once all the form is complete click the **Submit Form** button.

## Section 7: sIRB Closure Forms

Once a site is closed, the site cannot be re-opened. To re-open a site a new form must be created site fees will be charged.

## 7.1: Submitting a Closure form

1. After logging in to myIRB, navigate to the **myProjects** tab and then the **All Projects** tab. Click on the IRB ID # for the study.
2. From the Create Form section, click on **Site Project Closure Form**.

The screenshot shows the myIRB Project Summary page for a Biomedical project. The page is divided into several sections: Summary, Project Details, Attachments, Research Team, Funding, Sites, REFs, and Approval. The 'Create Form' section is highlighted, and the 'Project Close Form' link is circled in red. The 'Subjects' section shows 100 approved subjects, and the 'Federal Regulatory Oversight' section shows the '2018 Common Rule/Equivalent Protections' option selected.

Form	Received	Agenda Date	Type	Status	Basket	Other Review
<a href="#">sIRB Project New</a>	07/19/19		Exp	<a href="#">Approved on 07/19/19</a>		<a href="#">None</a>

3. Read the information and confirm you are ready to close.
4. Provide the requested information and use the **Continue/Save** buttons to move through the sections.
5. Once all the form is complete click the **Submit Form** button.

## Section 8: 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.

**Reliance Packet:** information provided to sites relying on the Washington University IRB. The packet may contain the reliance addendum, template consent form and local context questionnaire. External sites should provide this packet to their local IRB for completion.

**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.

## Section 9: Frequently Asked Questions

I don't remember my HRPO ID and/or password. What do I do?

See section 2.2, Number 3.

How does the PI "sign" a form?

See section 3.2, Numbers 6-8.

How do I find a draft form in myIRB?

See section 3.2, Number 5.

When should I work on my local IRB application?

WU sIRB recommends that you work on the local IRB submission and the Site Application simultaneously after the project level application has been approved. This is when sites will have access to project-level approved documents.