

WashU | **sIRB**

myIRB and Single IRB Reference Manual

for

LEAD PIs and Study Teams

**This manual should not be used by Washington University
Investigators or Participating Sites. If you need assistance contact
the WU IRB.**

WU Single IRB Contact

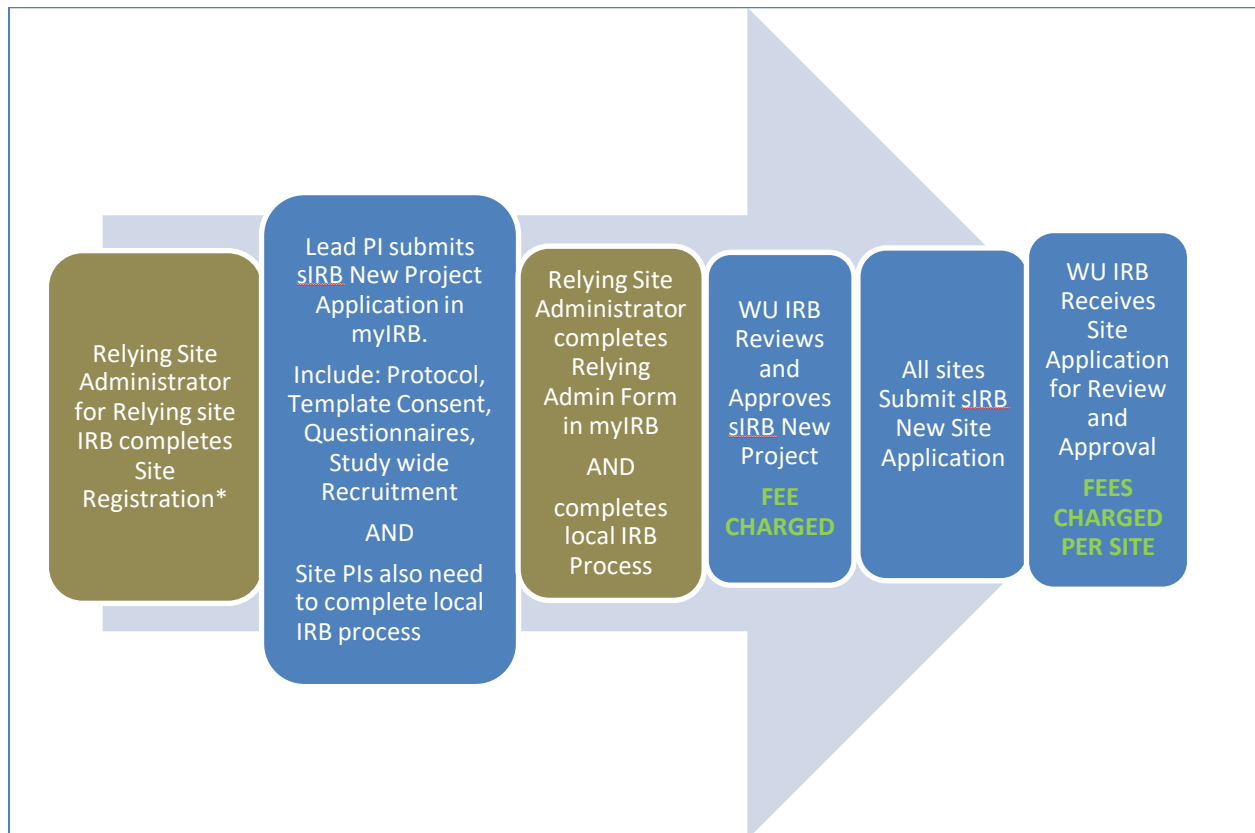
If you have questions, concerns, or suggestions regarding the sIRB process, please contact
Carissa Minder, at Carissa.minder@wustl.edu

Contents

Section 1: Washington University sIRB Review Process	4
1.1: Reliance Agreements	4
1.2: myIRB Technical Information	4
2.1 Request a HRPO ID.....	5
2.2: Logging in to myIRB	7
2.3: Delegates to the PI.....	9
Section 3: New Project Application	11
3.1: Completing the New Project Application.....	11
3.2: Addressing Questions from the WU sIRB.....	16
4.1: Site Applications	18
4.2: Submitting a Site Application	19
4.3: Reviewing Site Information	20
Section 5: sIRB Study Modifications	21
5.1: Submitting a Modification.....	22
Section 6: sIRB Continuing Review	26
6.1: Submitting a Continuing Review.....	27
Section 7: sIRB Reportable Events.....	31
7.1: Submitting a Reportable Event.....	31
Section 8: sIRB Closure Forms.....	32
8.1: Submitting a Closure form	32
Section 9: Definitions.....	33

Section 10: Frequently Asked Questions.....	35
---	----

Section 1: Washington University sIRB Review Process



* One Time Process. May Already be completed. WU IRB will provide specific instructions on what steps a Relying Institution Site Administer needs to complete on a study by study basis.

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

Request a HRPO ID Submit a request to HRPO for a myIRB account

Request Limited Access Submit a request to HRPO for a limited access myIRB account

© 2021 The University of Iowa, Washington University in St. Louis 03/01/21 10:43:14

3. Select the **Principal Investigator** or **Research Team** role depending on your role in the study 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. This usually happens within 1 business day.
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**

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

Request a HRPO ID Submit a request to HRPO for a myIRB account

Request Limited Access Submit a request to HRPO for a limited access myIRB account

© 2021 The University of Iowa, Washington University in St. Louis 03/01/21 10:43:14

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**

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

WUSTL Key

Login to myIRB using your WUSTL key credentials

BJC-NT User Login

BJC-NT User Login

Login to myIRB using your BJC credentials

HRPO ID Login

HRPO ID Login

Login to myIRB using your HRPO provided credentials

Request a HRPO ID

Request a HRPO ID

Submit a request to HRPO for a myIRB account

Request Limited Access

Request Limited Access

Submit a request to HRPO for a limited access myIRB account

© 2021 The University of Iowa, Washington University in St. Louis
5.49.0
03/01/21 10:43:14

- 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.

Please Sign In
Need Help?

Login using your myIRB HRPO ID credentials

Username:

Password:

[Forgot HRPO ID username?](#)
[Forgot HRPO ID password?](#)

For further assistance contact [HRPO](#).

© 2021 The University of Iowa, Washington University in St. Louis
5.49.0
03/01/21 11:08:42

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.

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) Click on the **Personalize** on the red menu bar at the top of the page.
- 2) Click on the gray button that says **Update my delegates**.
- 3) 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.
- 4) Click the **Add Delegate** button.

myIRB Washington University in St. Louis

myHome Create Project Search Reports Scheduling Admin Personalize Go Need Help?

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.

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	minderc@wusm.wustl.edu	remove

© 2021 The University of Iowa, Washington University in St. Louis 03/01/21 10:53:24

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 Washington University in St. Louis

myHome Create Project Search Reports Scheduling Admin Personalize Go Need Help?

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											

© 2021 The University of Iowa, Washington University in St. Louis 03/01/21 10:54:37

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

The screenshot shows the myIRB interface for Washington University in St. Louis. At the top, there is a navigation bar with 'myHome' and 'Personalize' tabs. Below this, a breadcrumb trail reads 'myIRB > Personalize > Delegate Login'. On the right, there are links for 'Delegate Minder', 'logout', and 'delegate login'. A message states: '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	carissa.minder@wustl.edu	login as Jonathan Himmel

At the bottom left, the copyright notice reads '© 2018 The University of Iowa, Washington University in St. Louis 5.30.0'. At the bottom right, the date and time are '08/29/18 12:16:11'.

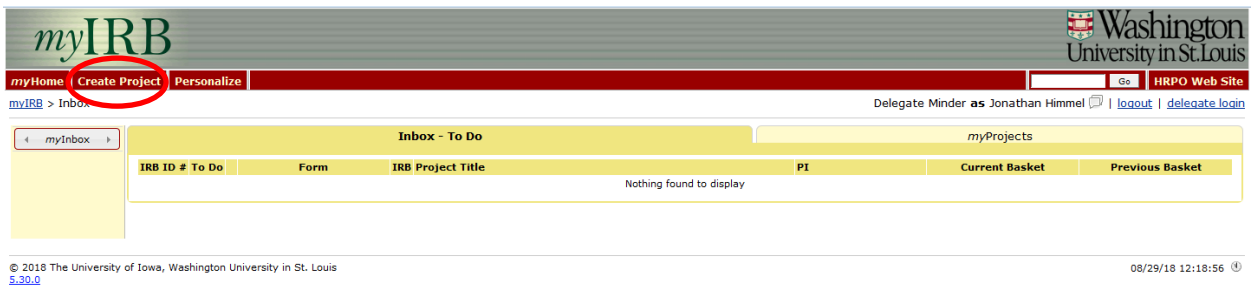
Section 3: New Project Application

The Project Application in myIRB should be used by the Lead PI or study team to submit the overall protocol to the WU sIRB for review. The approval of this application will not be for any one particular site but rather will be the study protocol overall.

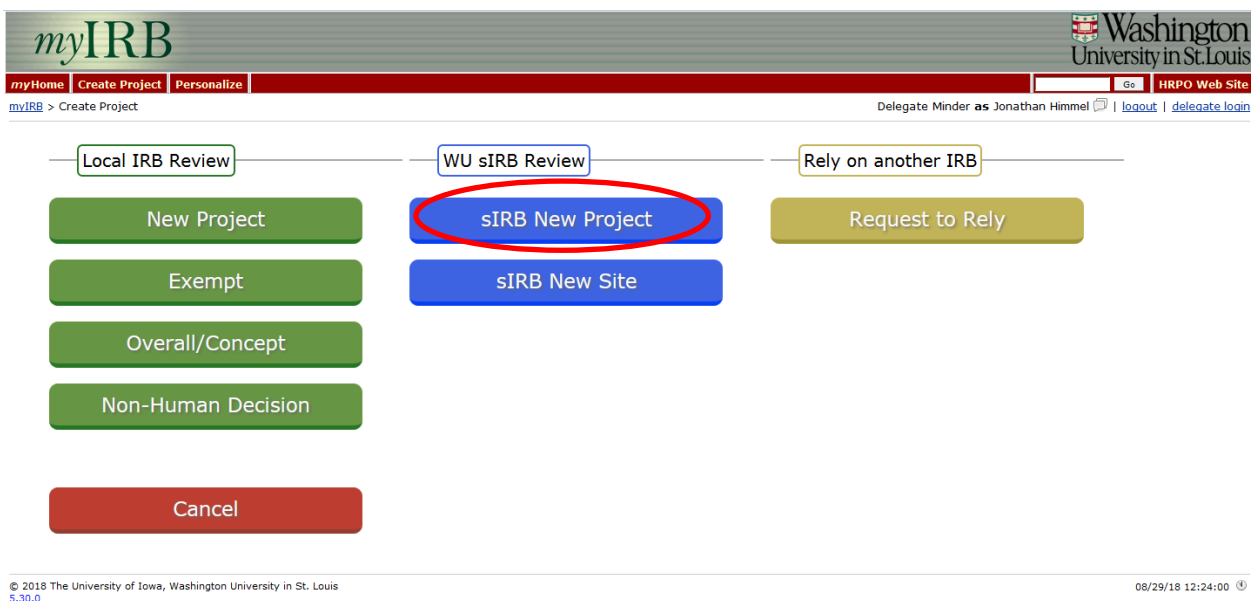
3.1: Completing the New Project Application

1. Log in to myIRB using your **HRPO ID** and password that you created (see Section 2.1).
<https://myirb.wusm.wustl.edu>

2. Select **Create Project** in the red menu bar at the top of the page.



3. Select **sIRB New Project**. You will be prompted to confirm your PI name and Institution.



- You will then enter the electronic application form. To work through the form, start by clicking on the blue **Demographics** link.

The screenshot shows the 'myIRB' interface for Washington University in St. Louis. The main heading is 'sIRB New project'. On the left, under 'myProject', there is a list of steps: 1. **Demographics** (circled in red), 2. Source(s) of Support, 3. Research Team, and 4. Other Information. The top navigation bar includes links: myHome, Create Project, Search, Reports, Scheduling, Admin, Personalize. The user is logged in as Julie Moyer. The page title is 'Unnamed Project'.

- You can begin answering questions about the project. 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**.

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

The screenshot shows the 'myIRB' interface for Washington University in St. Louis, specifically the 'Source(s) of Support' section. The 'Save' link is circled in red. The form includes fields for Type/Source, Grant Title/PI, and Status. The user is logged in as Jonathan Himmel. The page title is 'myProject 2. Source(s) of Support'.

- 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).

The screenshot shows the myIRB web application interface. At the top, there is a navigation bar with links: myHome, Create Project, Search, Reports, Scheduling, Admin, Personalize, and a search bar. Below this is a breadcrumb trail: myIRB > sIRB New Project Form > Source(s) of Support. The main content area is titled 'myProject 2. Source(s) of Support'. It contains a table with columns: Type/Source, Grant Title/PI, Status, and a link icon. The first row shows 'Federal Agency Maternal & Child Health (DHHS)' under Type/Source, 'Title: PI:' under Grant Title/PI, 'Just in Time' under Status, and 'Edit Remove' under the link icon. Below the table, there is a section titled 'Notice of Just in Time (JIT) Documentation' with a table for attachments. The 'Upload file(s)' link is circled in red.

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

Notice of Just in Time (JIT) Documentation				
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)				

6. You 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.
7. If a consent form is required for this study, you will be required to submit a template study consent for approval by the WU IRB. You are required to use the Washington University Informed Consent template that is available in myIRB. From the **Attachments** page, use the drop down menu and click the **Select Template** button to choose the appropriate generic consent document to begin creating your template study consent. When the template consent is ready to upload, use the **Click here to ADD or DELETE attachments** link to attach the document.

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 IRB members and others) ?

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

Attachment Name	Category	Ver	Size	Attached
No attachments found				
Click here to ADD or DELETE attachment(s)				

NOTE: Consent files uploaded to myIRB as attachments need to contain a gray IRB stamp box and be in .rtf file format in order to be attached to the application.

- 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.

myProjects

Inbox - To Do **Draft Forms** Pending Forms All Projects

IRB ID #	IRB Title	Form
Unnamed Project	Unnamed Project	New
BIO HSD	Unnamed Project	New
BIO 4.9	Unnamed Project	New
BIO ed	Unnamed Project	New
Unnamed Project	Unnamed Project	New
Unnamed Project	Unnamed Project	HSRD
Unnamed Project	Unnamed Project	sIRB Project New
BIO BTR TEST	Unnamed Project	New
BIO Use of Pull ICF	Unnamed Project	New
Unnamed Project	Unnamed Project	New
Unnamed Project	Unnamed Project	New
BIO d	Unnamed Project	New
Unnamed Project	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. The PI will receive an email from

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

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 -->](#)

© 2018 The University of Iowa, Washington University in St. Louis 08/29/18 02:57:19

- The PI can either click on the link in the myIRB@wusm.wustl.edu email and enter their HRPO ID and password, OR, they can log in to myIRB using their 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

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

© 2020 The University of Iowa, Washington University in St. Louis 02/19/20 02:43:18

- 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](#)

© 2018 The University of Iowa, Washington University in St. Louis
5.30.0

08/31/18 11:02:54

12. At this point, a notice will be sent to your local IRB office administrator letting them know a PI from their institution has submitted a form to the WU sIRB. The local IRB administrator will then log in to the system to assess the information and complete the electronic sign off process to defer to the WU sIRB for this study. Once they have completed that process, the study will move on to the WU sIRB office for review.

3.2: Addressing 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 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.

myIRB Washington University in St. Louis

myHome Create Project Personalize Go HRPO Web Site

myIRB > Inbox Delegate Minder as Jonathan Himmel | logout | delegate login

Inbox - To Do				myProjects		
IRB ID	To Do	Form	IRB Project Title	PI	Current Basket	Previous Basket
201800021	Regular	sIRB New	BIO Manual	Jonathan Himmel	PI Review	Admin Prescreen

© 2018 The University of Iowa, Washington University in St. Louis 08/31/18 09:20:27

- 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.

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.

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.

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.

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.

Correspondence From: Christine Bear
Contact Email: carmena@wusm.wustl.edu
Phone: 314/362-1175

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.

☐ I have made the requested attachment changes
☐ I have not made the requested attachment changes, see comments

Enter any comments about your change(s) here:

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.)

[Save Answers to Correspondence](#)

[Click here](#) to review past correspondence with HRPO for this routing slip.

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.

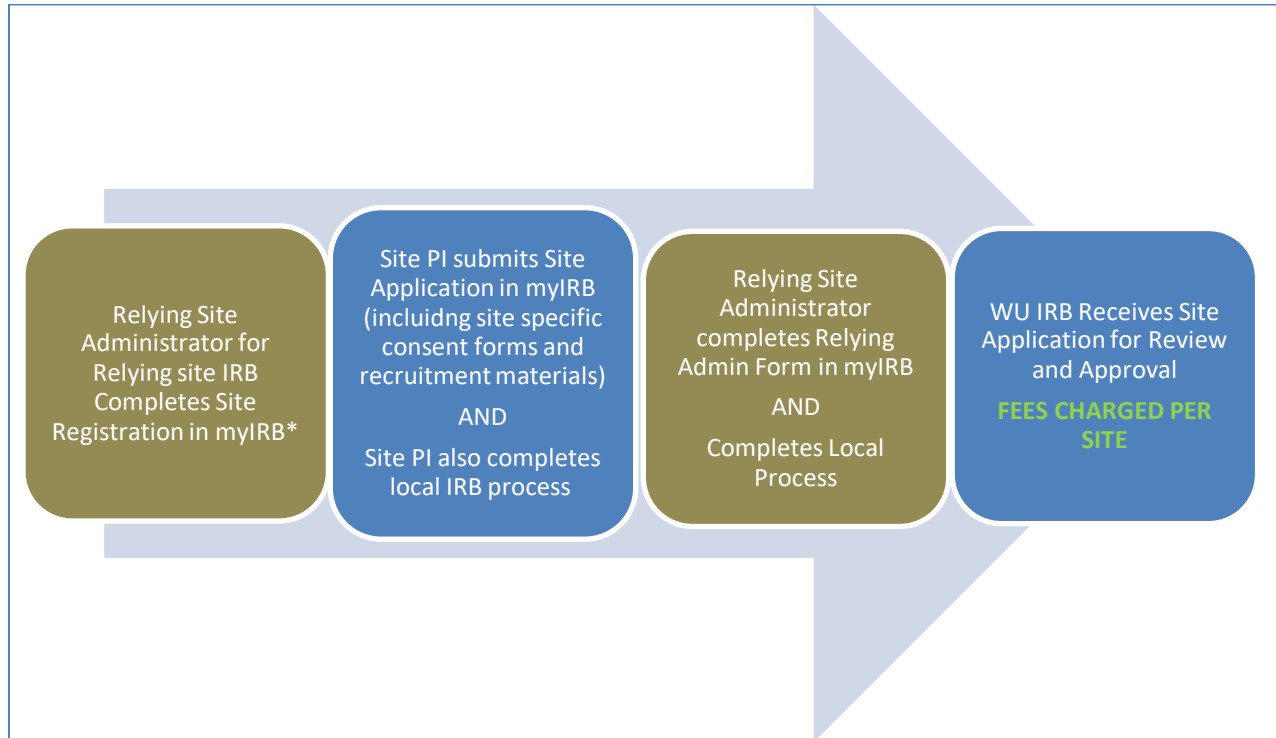
[Return form and my answers](#)

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.

- The PI and their delegates will receive a notification email from myIRB@wusm.wustl.edu when the project application has been approved by the WU IRB.

Section 4: Site Submissions and Site Management



*One Time Process. May Already be completed. HRPO will send site instructions, when applicable.

4.1: Site Applications

1. All sites, including the lead site, will need to submit an **sIRB New Site** application to obtain approval to conduct the research at their site. Once the **sIRB New Project** is approved by the WU IRB, HRPO will request that the study team provide a list of sites and site contact information using an excel spreadsheet provided by HRPO to the study team via email. HRPO will email the site PI's, study team contacts, and site IRB with specific instructions on how to submit a sIRB New Site application.
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 should NOT attach a consent form. If a local site requires a consent form, the WU sIRB will use the approved project consent template and insert site-specific required language in to the consent and then provide it to the local New Site. (Site-specific language is provided by the local site's IRB using the Site Registration process.)

4.2: Submitting a 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 interface for Washington University in St. Louis. The top navigation bar includes 'myIRB', 'Create Project' (circled in red), 'Personalize', and a search bar. Below the navigation bar, there are three tabs: 'Local IRB Review', 'WU sIRB Review', and 'Rely on another IRB'. Under the 'WU sIRB Review' tab, there are three buttons: 'sIRB New Project', 'sIRB New Site' (circled in red), and 'Request to Rely'. On the left side, there are four green buttons: 'New Project', 'Exempt', 'Overall/Concept', and 'Non-Human Decision'. At the bottom, there is a red 'Cancel' button. The footer contains copyright information and a timestamp.

2. You will be prompted to confirm your site PI name and Institution. You will be asked for the IRB ID #.
3. Do NOT attach any questionnaires or study-wide recruitment documents that have already been approved.
4. Do attach any site-specific documents such as recruitment documents.
5. Complete the Site Application questions, have the PI sign and submit as was done for the New Project application.
6. You will receive a notification email from myIRB@wusm.wustl.edu when the site application has been approved.

4.3: Reviewing Site Information

1. As the lead PI, you can track and review site status and all submitted information in myIRB. From the **Project Summary** page click on the **Sites** tab. You will be taken to a listing of sites. You can click on the IRB ID # link to view site specific information. You can use this information to follow up with sites who have not completed their applications.

The screenshot shows the myIRB Project Summary page for a Biomedical project (201810003). The 'Sites' tab is highlighted with a red circle. The page displays project details, a list of subjects, FDA and other review information, and a history table.

myIRB Washington University in St. Louis

myHome Create Project Personalize 201810003 Go! HRPO Web Site

myIRB > Project Summary Jonathan Himmel | logout | delegate login

Summary Project Details Attachments Research Team Funding **Sites** REFs Approval

IRB: Biomedical
IRB ID #: 201810003
Title: Kidney Precision Medicine Project
Short Title: Kidney Project
PI: Jonathan Himmel
Status: Open
Site: University Of Washington

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

Subjects
Approved: 1500
Minors: N/A
Pregnant/Fetus: No
Cognitively Impaired: No
Prisoners: No

FDA
IND Numbers: No
IDE Number: N/A
HDE Number: N/A
Non-Significant Risk Device: N/A
Emergency Use: N/A

Review
Next Approval Due By: 10/10/19
Closed to Accrual: No

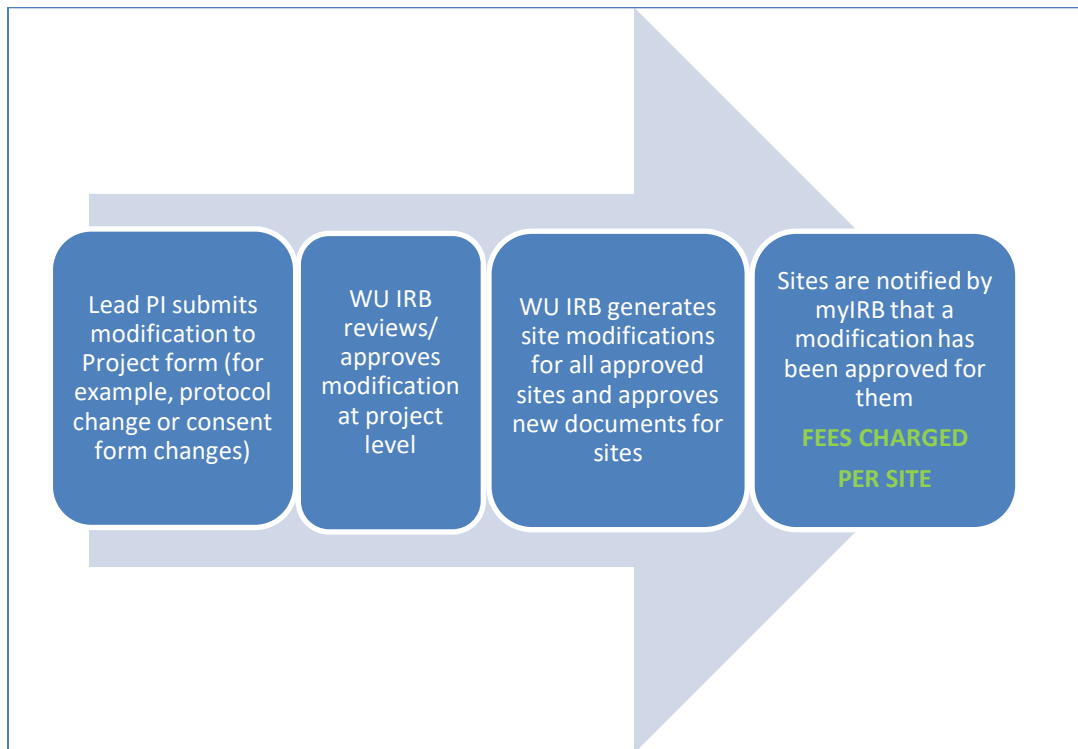
Other
Certificate of Confidentiality: Received
IRB Authorization Agreement: N/A
Unaffiliated Investigator Agreement: N/A

History History Filter: Project Form

Form	Received	Agenda Date	Type	Status	Basket	Other Review
sIRB New	10/11/18		Exp	Approved on 10/11/18		None

© 2018 The University of Iowa, Washington University in St. Louis 5.30.0 10/11/18 11:06:23

Section 5: sIRB Study Modifications



1. Changes that need to be made to the protocol or other study-wide information should be submitted by the lead site as a modifications to the project application.
2. Once the modification of the project application is approved, modifications will be automatically generated for each site and approved.
3. Sites will be notified of the modifications and will need to log in to myIRB to obtain any updated documents.
4. 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.

5.1: Submitting a Modification

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

The screenshot shows the myIRB homepage for Washington University in St. Louis. The top navigation bar includes links for myHome, Create Project, Personalize, and a search bar. Below the navigation bar, there's a section for 'Inbox - To Do' with a table listing projects. The 'myProjects' link in the top right navigation bar is circled in red.

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

2. Click on **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 Project Summary page for 'Abby's Test'. The page has tabs for Summary, Details, Attachments, Research Team, Funding, REFs, Approval, and Protocol. The 'Summary' tab is active. In the 'Create Form' section, the 'Modification/Update Form' link is circled in red.

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

4. A copy of your currently approved application is created as a draft to modify. Use the links to navigate to the appropriate sections of the application and make the required updates.

The screenshot shows the 'myProject' interface for the 'Kidney Project' on the 'sIRB Site'. At the top, there are tabs for '1', '2', '3', and '4', followed by 'Note Summary' and 'Error Check'. Below these, a box titled 'myProject' contains a list of four items, each with a green checkmark: '1. Demographics', '2. Source(s) of Support', '3. Research Team', and '4. Other Information'. To the right, there is a button labeled 'Go to the myIRB application' with a red arrow, and another button labeled 'IRB application'. Below the 'IRB application' button are two buttons: 'Draft' and 'Pending'. Further right, it says 'sIRB site: University Of Washington'. At the bottom left, there is a copyright notice: '© 2021 The University of Iowa, Washington University in St. Louis' and a version number '49.0'.

5. 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.

The screenshot shows the 'myIRB' interface for the 'Kidney Project'. At the top, there is a navigation bar with links: 'myHome', 'Create Project', 'Search', 'Reports', 'Dept Reports', 'Scheduling', 'Admin', and 'Personalize'. To the right of the navigation bar is a search box with the text '201810003' and a 'Go' button, and a link to 'HRPO Web Site'. Below the navigation bar, it says 'myIRB > sIRB Project Modification Form > Project Summary'. On the right side, there is a 'Change Form' section with three radio buttons: 'Modification/Update Only' (selected), 'Continuing Review Only', and 'Both', and a 'Change' button. The main content area has two tabs: 'Modification Index' and 'Continuing Review Index'. Below the tabs, there is a 'Back to Project Index' link. In the center, there is a 'myIRB' box with a list of three items, each with a green checkmark: '1. Protocol', '2. Participants', and '3. Performance Sites'. To the right of the 'myIRB' box is a red arrow pointing to the right. Below the 'myIRB' box, there is a 'review' link. At the bottom left, there is a copyright notice: '© 2019 The University of Iowa, Washington University in St. Louis' and a version number '5.39.0'. At the bottom right, there is a timestamp: '05/23/19 03:35:25'.

6. 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 and save a copy to your computer. Make the appropriate edits using TRACKED CHANGES.

7. 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

Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers. (section requiring attachment)

Generate Standard Blank Template

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

Click here to ADD or DELETE attachment(s)

Attachment Name	Category	Ver	Size	Attached
blank template.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	38 k E	10/11/18 EDIT

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

Attachment Name	Category	Ver	Size	Attached
MU Kanne Appendix J.1.a Invitation Call Script - POP source selection SEED 3 MO SEED 09.12.18.rtf	Separate Written Protocol	1	688 k	10/11/18 delete EDIT
COVET STUDY PROTOCOL AMENDMENT 2 08Dec2017.pdf	Subject Data Collection Instruments	1	503 k	10/11/18 delete EDIT
TC SEED Social Story 09.12.18.docx	Curriculum Vitae of Principal Investigator	1	7 M	10/11/18 delete EDIT
assurance-document.rtf	Listing of Data/Specimen Data Points	1	89 k	10/11/18 delete EDIT

assurance-document.rtf

Assurance Document

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 5.39.0 05/23/19 03:40:46

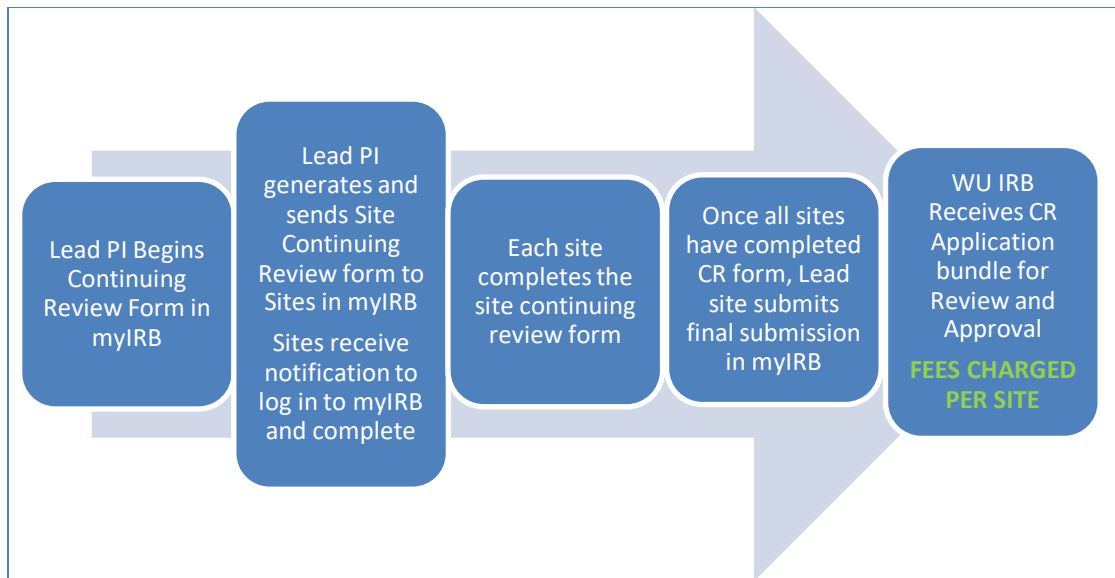
9. Once you have completed your changes, click on the **Review & Submit** button.

The screenshot shows the myIRB web application interface. At the top, there is a navigation bar with links like myHome, Create Project, Search, Reports, Dept Reports, Scheduling, Admin, and Personalize. The user is logged in as Jonathan Himmel. The main content area is titled 'Kidney Project' and shows a 'Modification Index' with tabs for 1 through 6. The 'Review & Submit' button is circled in red. Below the index, there are three boxes labeled '1. Protocol', '2. Participants', and '3. Performance Sites', each with a 'review' link. A red arrow points from the 'Review & Submit' button to the '3. Performance Sites' box.

Review the changes and click the **Route Form for Signature button** and enter in your HRPO ID and password. The modification is now delivered to the PI for signature. The PI will be notified by email that their signature is required to submit the modification for WU IRB review.

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

Section 6: sIRB Continuing Review



1. The Lead PI will receive a notice when the continuing review of a study is due. The Lead PI will need to log in to myIRB and start the continuing review form.
2. At the end of the form, the Lead PI will click the button generating the site portions of the continuing review forms.
3. The Site PIs will receive notice that they need to log in to myIRB and complete their portion of the continuing review form.
4. Once all sites have completed their continuing reviews, the Lead PI will log back in to myIRB and submit the combined continuing review form.
5. The Lead PI should plan to have resources and time available at the time of the continuing review to assist and follow up with sites to ensure they complete their required form. They are able to review the site status and completed forms for all sites in myIRB.

6.1: Submitting a Continuing Review

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. You will be directed to the Project Summary Page.
2. In the Create Form Box, click on **Continuing Review Form**.

myIRB Washington University in St. Louis

myHome Create Project Personalize 201907026 Go Help

myIRB > Project Summary ben powell | logout | delegate login

Summary		Project Details	Attachments	Research Team	Funding	Sites	REFs	Approval
IRB		Biomedical						
IRB ID #		201907026						
Title		STUDY FOR DEMONSTRATIONS	Create Form					
Short Title		DEMO FOR CARISSA	Continuing Review Form					
PI		ben powell	Response Form					
Status		Open	Project Close Form					
Site		Abby's Test (1021)						
Subjects								
# Approved	100							
Minors	N/A							
Pregnant/Fetus	No							
Cognitively Impaired	No							
Prisoners	No							
Review								
Next Approval Due By								
Closed to Accrual	No							
Federal Regulatory Oversight								
Yes No								
<input checked="" type="radio"/> FDA								
<input type="radio"/> OHRP								
<input checked="" type="radio"/> 2018 Common Rule/Equivalent Protections - 7/19/19								
<input type="radio"/> Pre-2018 Common Rule/Equivalent Protections								
History								
Form	Received	Agenda Date	Type	Status	Basket	Other Review	History Filter: Project Form	
sIRB Project New	07/19/19		Exp	Approved on 07/19/19		None		

© 2019 The University of Iowa, Washington University in St. Louis 12/10/19 02:17:01

3. Click on **CR 1. Project Summary** to start completing the application. Answer the questions and click **Continue/Save** to move to additional questions in CR 2.
4. When you are ready to send the sites their CR forms to complete, navigate to section **CR 3** and click the gray button that says **Create Site Continuing Review Forms**. The site PIs and delegates will receive an email telling them to log in and answer the questions specific to their site.

myIRB Washington University in St. Louis

myHome Create Project Personalize 201907026 Go Help

myIRB > sIRB Project Continuing Review Form > Site CR forms ben powell logout | delegate login

<-- Back/Save Index/Save Save and Remain Continue/Save --> [103]

CR 3. Site CR forms

☐ **CR 3.1** Date/time when the site Continuing Review forms were created:
The site Continuing Review forms have not been created yet. Click the button below to create the site Continuing Review forms and send the site CR 3 notification:

[Create Site Continuing Review Forms](#)

☐ **CR 3.2** Continuing Review forms for the sites associated with this protocol:

<-- Back/Save Index/Save Save and Remain Continue/Save --> [103]

© 2019 The University of Iowa, Washington University in St. Louis 12/10/19 02:22:06

- If there are documents that need to be attached, please attach them on the **Attachments** page at the end of the application. If myIRB is not prompting you to attach anything, no attachments are needed.

- You will not be able to submit the form or route the form for signature until all the sites have completed their Site CR form.

NOTE: You will also need to submit your own Site CR form that will be generated. To complete this, go to the PI's Inbox and click on the file folder icon under the **To Do** heading.

myIRB Washington University in St. Louis

myHome Create Project Personalize Go Help

myIRB > Inbox ben powell logout | delegate login

myInbox

Inbox - To Do				myProjects		
IRB ID #	To Do	Form	IRB Project Title	PI	Current Basket	Previous Basket
201810003-102	Regular	sIRB Site New	BIO Kidney Project	ben powell	Relying Admin Pending	PI Signature Requested
201809001-102	Regular	sIRB Site New	BIO In Meeting Test	ben powell	Relying Admin Pending	PI Signature Requested
201901032-102	Regular	sIRB Site CR	BIO test for prod	ben powell	Protocol CR Pre Submit	

© 2019 The University of Iowa, Washington University in St. Louis 12/10/19 03:07:18

- 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.

myIRB
CR 1 | CR 2 | CR 3 | Review & Submit

CR 1. Project Summary

CR 2. Current Enrollment

CR 3. Progress Report

review

© 2019 The University of Iowa, Washington University in St. Louis
5.44.0

12/10/19 03:10:55

- 2) When complete, click the **Route form for signatures** button and have the form signed by the PI.

7. To check the status of site CR forms, go to the draft CR form, then to Section CR 3. Site form sections are green when complete. The signature status will either be **Signed by Site PI** or **Signature Pending**. When all sites are complete and signed, click **Continue/Save** and have the Project CR form signed by the Lead PI. The Project CR form and all the Site CR forms will be sent to the WU IRB for review.

myIRB
CR 1 | CR 2 | CR 3 | view this form

Other Reviews: None

Non-responsive: ☐

Signature Pending

CR 1 | CR 2 | CR 3 | view this form

Other Reviews: None

Non-responsive: ☐

© 2019 The University of Iowa, Washington University in St. Louis
5.44.0

12/10/19 03:21:50

8. If a site is non-responsive and the CR form needs to be submitted, you are able to submit without them by selecting the **Non-responsive** box next to their site. This will prevent

them from getting re-approved so please discuss with the WU IRB staff before choosing this option.

9. The Project CR and all the site forms will be reviewed together and if the CR is approved, the lead PI and their delegates will receive an email from myIRB@wusm.wustl.edu. If there are required actions following the committee meeting, the PI and their delegates will be notified by email.

Section 7: sIRB Reportable Events

Reportable Events can be submitted at both the Project and Site level. The type of event will determine if it is more appropriate to submit at that Project level (the event affects the whole study) or Site level (affects only one site). The WU IRB Reporting Requirements must be followed, and Sites may also have reporting requirements they must follow locally.

7.1: 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 Project Summary page for a project titled "STUDY FOR DEMONSTRATIONS". The "Create Form" section is highlighted with a red circle, showing options: "Modification/Update Form", "Continuing Review Form", "Reportable Event Form" (circled in red), and "Project Close Form".

Project Details:

- IRB ID #: 201907026
- Title: STUDY FOR DEMONSTRATIONS
- Short Title: DEMO FOR CARISSA
- PI: ben powell
- Status: Open
- Site: Abby's Test (1021)

Subjects:

- # Approved: 100
- Minors: N/A
- Pregnant/Fetus: No
- Cognitively Impaired: No
- Prisoners: No

Review:

- Next Approval Due By: Closed to Accrual
- Closed to Accrual: No

Federal Regulatory Oversight:

- Yes ☐ No ☒
- ☒ FDA ☐ OHRP
- ☒ 2018 Common Rule/Equivalent Protections - 7/19/19
- ☐ Pre-2018 Common Rule/Equivalent Protections

History:

Form	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 8: sIRB Closure Forms

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

8.1: 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 **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 Summary section is currently selected. It displays project information such as IRB ID # 201907026, Title STUDY FOR DEMONSTRATIONS, and PI ben powell. The 'Create Form' section is highlighted with a red circle, showing links for 'Modification/Update Form', 'Continuing Review Form', 'Research Change Form', and 'Project Closure Form'. The 'Project Closure Form' link is circled in red. Below this, there are sections for Subjects, Review, Federal Regulatory Oversight, and History. The History section shows a table with columns for Form, Received, Agenda Date, Type, Status, Basket, and Other Review. The table contains one entry: sIRB Project New, Received 07/19/19, Type Exp, Status Approved on 07/19/19, Basket None, and Other Review None.

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.

Once all the form is complete click the **Submit Form** button.

Section 9: 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 is 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 interest management plans have been provided. Additionally, this form confirms the Relying Site agrees to defer to the WU IRB for the particular study.

Section 10: Frequently Asked Questions

I don't remember my HRP0 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.

Why don't I need to attach a consent document with my New Site application?

The WU sIRB will attach the site consent document for all site applications. See section 3.5.

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.

