

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

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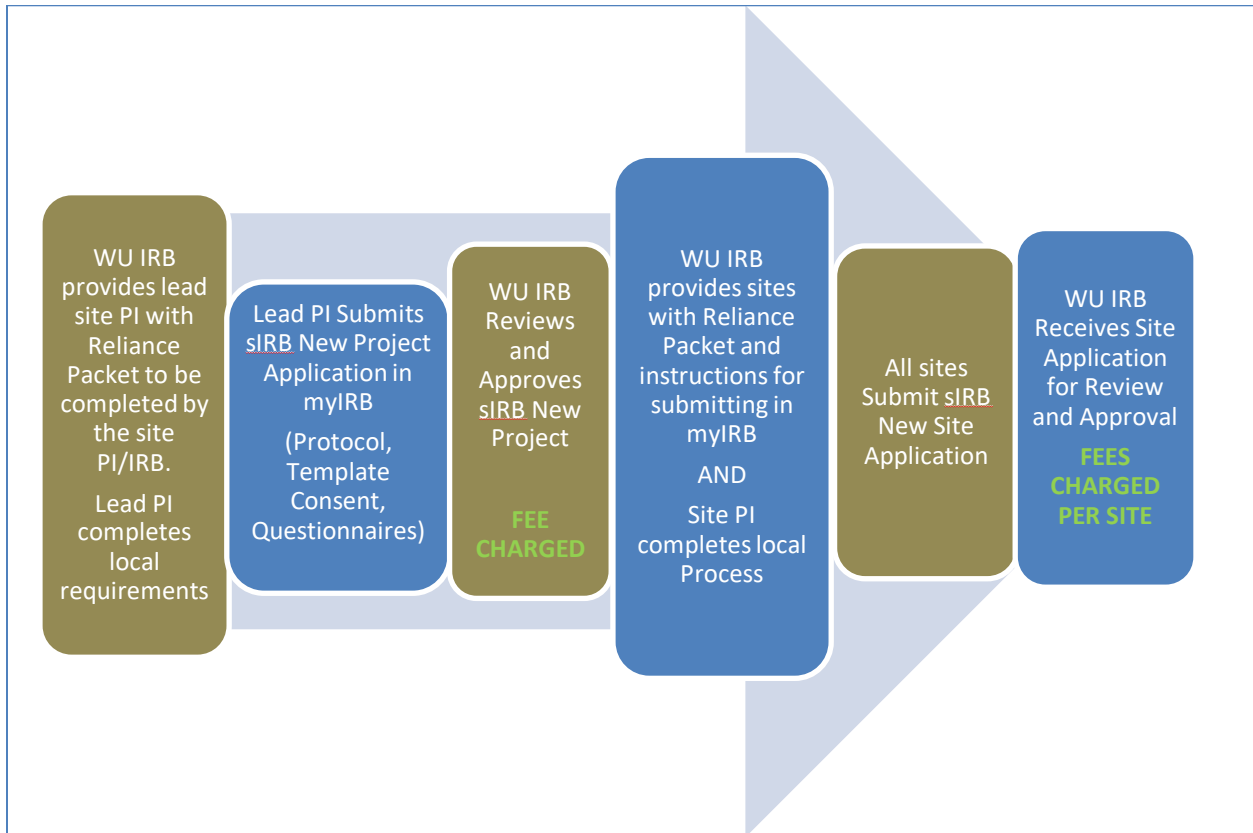
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Section 1: Washington University sIRB Review Process



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

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

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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

Please Sign In

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 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**

Welcome to *myProject* and *myIRB*

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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

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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?

Welcome to myProject and myIRB

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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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- 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.

myIRB Washington University in St. Louis

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](#).

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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. External study team members who need access to the myIRB materials or application should be named as a delegate for the PI.

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.

The screenshot shows the myIRB interface. At the top, there's a navigation bar with 'myIRB' logo and 'Washington University in St. Louis' branding. Below that is a red menu bar with options like 'myHome', 'Create Project', 'Search', 'Reports', 'Scheduling', 'Admin', and 'Personalize'. The user is logged in as Julie Moyer. The main content area is titled 'User Delegates'. It contains a search box with the text 'Add Delegate' highlighted in red. Below the search box, there's a table of current delegates:

Name	Department	Email	
Carissa Minder	Human Research Protection Office	minderc@wusm.wustl.edu	remove

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.

The screenshot shows the myIRB interface. At the top, there's a navigation bar with 'myIRB' logo and 'Washington University in St. Louis' branding. Below that is a red menu bar with options like 'myHome', 'Create Project', 'Search', 'Reports', 'Scheduling', 'Admin', and 'Personalize'. The user is logged in as Julie Moyer. The main content area is titled 'Inbox - To Do'. It contains a table with columns for 'IRB ID #', 'Entity', 'To Do', 'Workflow notes', 'Days in workflow', 'Form', 'IRB Project Title', 'PI', 'Current Basket', 'Previous Basket', 'From', and 'When'. The 'delegate login' link in the top right corner is highlighted in red.

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' buttons, a search box, and links for 'HRPO Web Site', 'Delegate Minder', 'logout', and 'delegate login'. Below the navigation bar, 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, there is a copyright notice: '© 2018 The University of Iowa, Washington University in St. Louis 5.30.0'. At the bottom right, there is a timestamp: '08/29/18 12:16:11'.

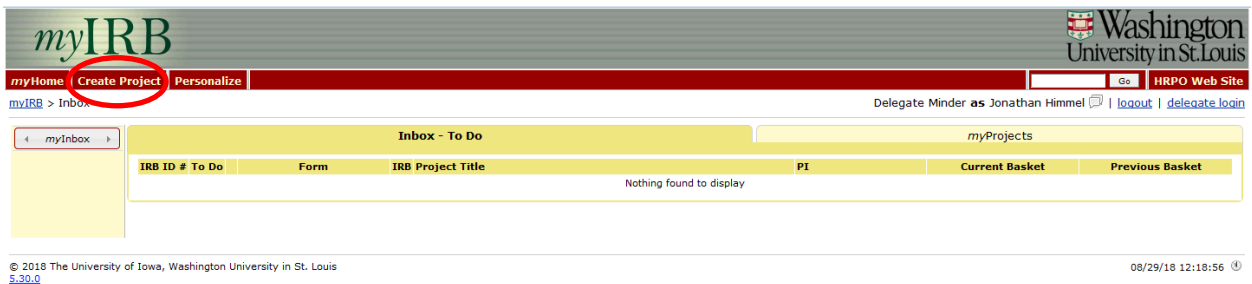
Section 3: New Project Application

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 for the study protocol overall. Each site (including the lead site) must submit a New Site Application for research to occur at their site. The project application is not approval to conduct research at any site.

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.

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

5. 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**.

- 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.

myIRB Washington University in St. Louis

myHome Create Project Personalize

myIRB > sIRB New Project Form > Source(s) of Support Delegate Minder as Jonathan Himmel | logout | delegate login

<< Back/Save Index/Save Save and Remain Continue/Save --> [102]

myProject 2. Source(s) of Support

Type/Source	Grant Title/PI	Status
Type: Federal Agency Source: NIH, National Institute on Aging (NIA) If you cannot find your source of support in the drop-down list above, enter it here: [Text Field]	Title: Grant Title [Text Field] characters remaining: 489 of 500 PI: George Washington	Awarded

+ Save Cancel

<< Back/Save Index/Save Save and Remain Continue/Save --> [102]

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- 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 Washington University in St. Louis

myHome Create Project Search Reports Scheduling Admin Personalize

myIRB > sIRB New Project Form > Source(s) of Support Julie Moyer | login as another user | logout | delegate login

<< Back/Save Index/Save Save and Remain Continue/Save --> [106]

myProject 2. Source(s) of Support

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

<< Back/Save Index/Save Save and Remain Continue/Save --> [106]

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- 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.
- 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.

myIRB Washington University in St. Louis

myHome Create Project Personalize

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

Delegate Minder as Jonathan Himmel | logout | delegate login

<- Back/Save Index/Save Save and Remain Continue/Save -->

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](#)

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

Other Supporting Documents

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.

- 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 requesting an electronic signature. The PI can also log in to myIRB and complete this request.

- 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 > 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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11. 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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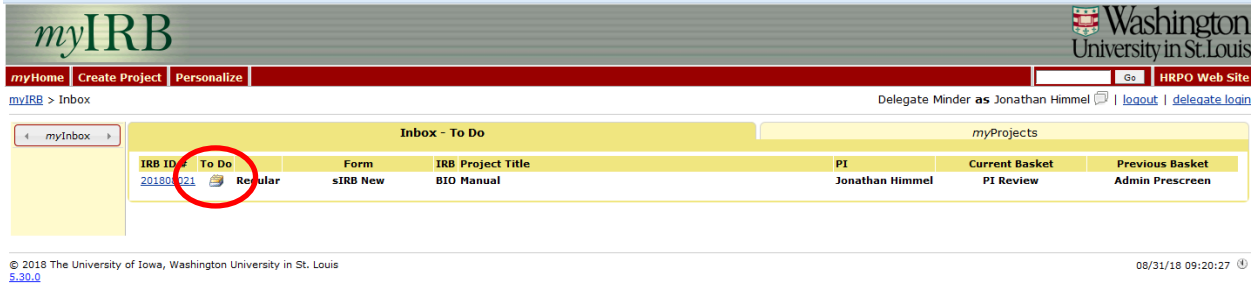
08/31/18 11:02:54

3.2: Addressing Questions from the WU sIRB

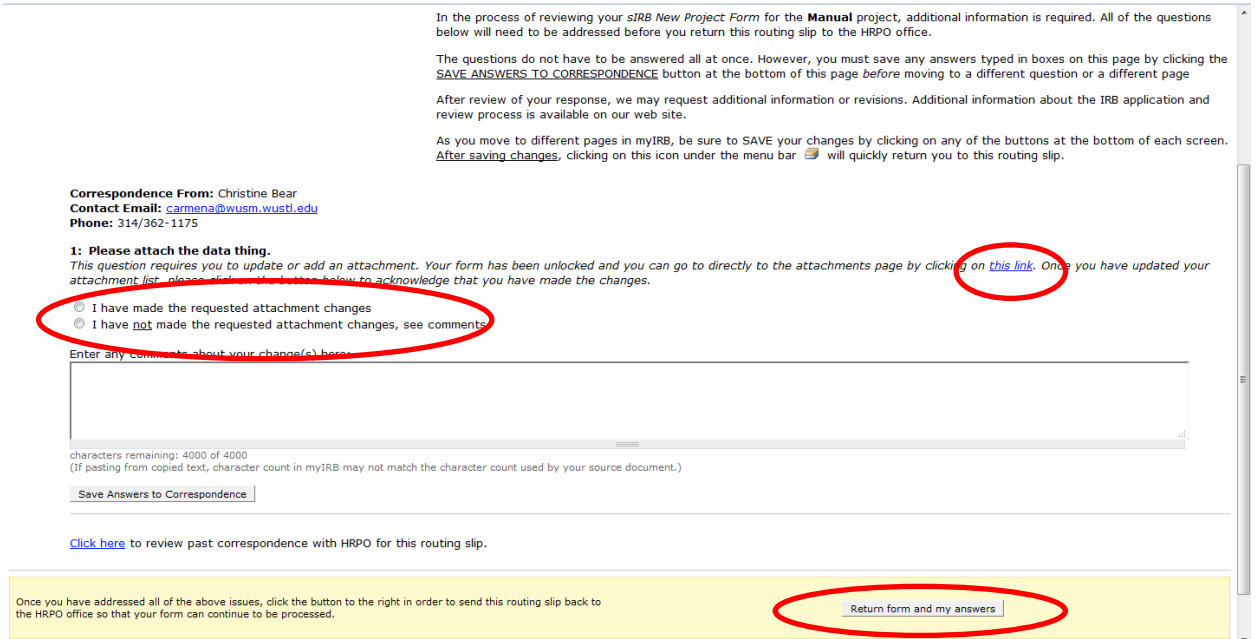
1. If the WU sIRB has questions about your application, you will be contacted through the myIRB system. The PI and their delegates will receive an email from myIRB@wusm.wustl.edu notifying them that there are contingencies to address.

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).

- 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.



- 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.

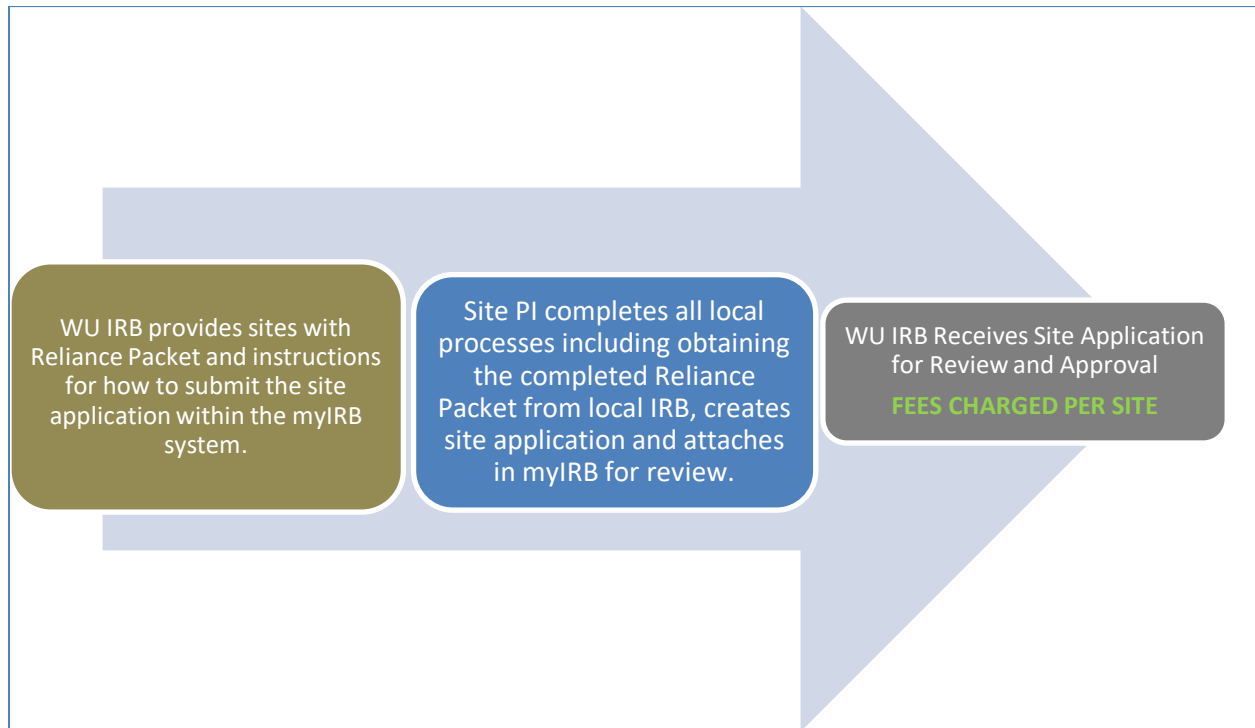


Make the changes to the application and click **Index/Save**. Navigate back to the **Workflow** page with the questions or requested changes using the file folder icon in the upper right hand corner of the page under the red menu bar.

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 when the project application has been approved by the WU IRB.

Section 4: Site Submissions and Site Management



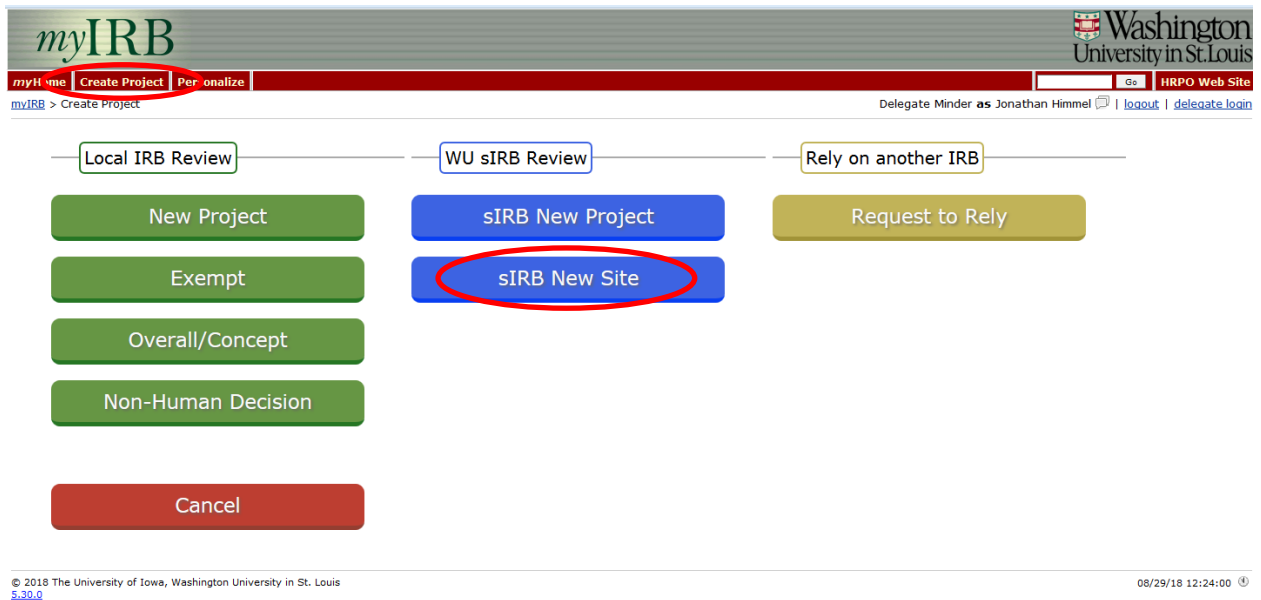
4.1: Site Applications

1. All sites, including the lead site, will need to submit a **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 and study team contacts with specific instructions on how to submit a sIRB New Site application and the Reliance Packet.
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.

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 site-specific information for the consent and local context form.

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**.



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 other documents that have already been approved at the project level.
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. Re-attach the completed Reliance Packet that was completed when your site submitted the Project Level Application.
6. You will receive a notification email from myIRB@wusm.wustl.edu when the site application has been approved.

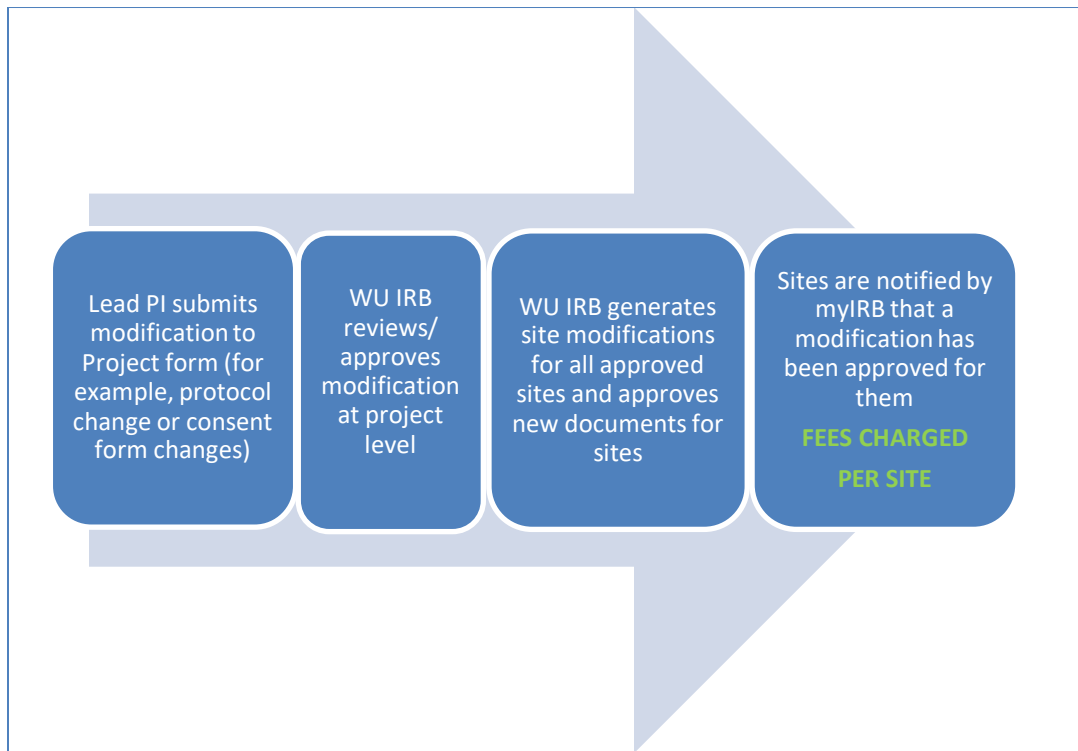
4.3: Reviewing Site Information

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.
2. All sites that have at least started a draft site application will appear in this list. If you do not see a site within this list, they have not started a draft application or submitted to the WashU IRB.
3. This tab also allows the lead study team to monitor site modifications.

The screenshot shows the myIRB Project Summary page for a Biomedical project (IRB ID # 201810003). The 'Sites' tab is highlighted with a red circle. The page includes sections for project details, subjects, FDA information, review dates, and a history table.

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

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 modification 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**.

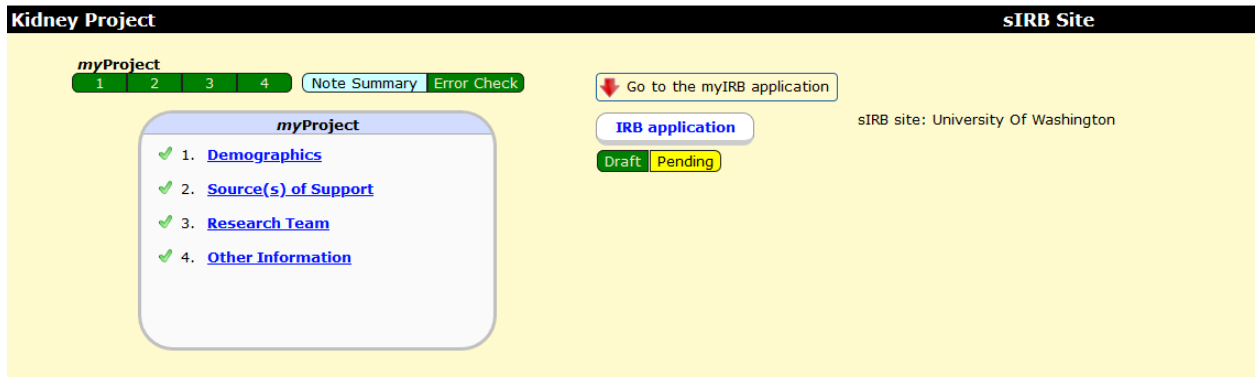
The screenshot shows the myIRB interface. At the top, there's a navigation bar with 'myHome', 'Create Project', and 'Personalize'. Below that, a breadcrumb trail reads 'myIRB > Inbox'. The main content area is titled 'Inbox - To Do' and contains a table with columns: IRB ID #, To Do, Form, IRB Project Title, PI, Current Basket, and Previous Basket. A row is visible with IRB ID # 201808021, To Do Regular, Form sIRB New, IRB Project Title BIO Manual, PI Jonathan Himmel, Current Basket PI Review, and Previous Basket Admin Prescreen. A red circle highlights the 'myProjects' link in the top right corner of the main content area.

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.

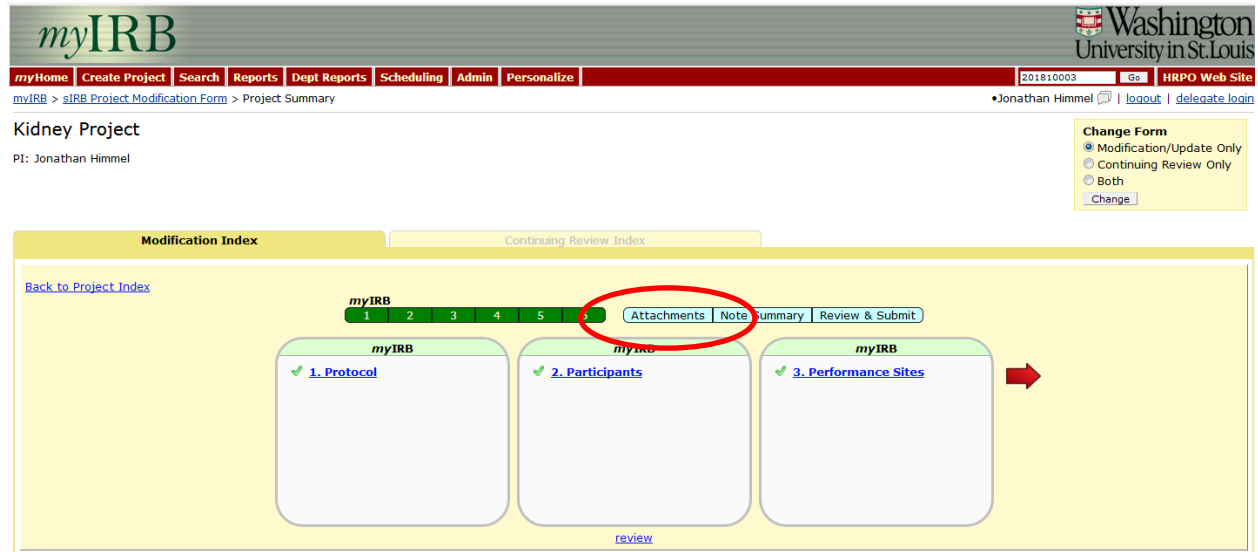
The screenshot shows the 'Project Summary' page for IRB ID # 201810003-1021. The page has a navigation bar with 'myHome', 'Create Project', and 'Personalize'. Below that, a breadcrumb trail reads 'myIRB > Project Summary > Site Project Summary - Abby's Test'. The main content area is titled 'Summary' and contains a table with columns: Summary, Details, Attachments, Research Team, Funding, REFS, Approval, and Protocol. A row is visible with IRB ID # 201810003-1021, Title Kidney Precision Medicine Project, Short Title Kidney Project, PI ben powell, Status Pending, and Site Abby's Test. A red circle highlights the 'Modification/Update Form' link in the 'Create Form' section of the table.

- 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.



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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 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.

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.

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.

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)

Other Supporting Documents

Tips for stamped recruitment materials

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

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

MU Kanne Appendix J.1.a Invitation Call Script - POP source selection SEED 3 MO SEED 09.12.18.rtf	Separate Written Protocol				10/11/18 delete EDIT
COVET STUDY PROTOCOL AMENDMENT 2_08Dec2017.pdf	Subject Data Collection Instruments	1	688 k		10/11/18 delete EDIT
TC SEED Social Story 09.12.18.docx	Curriculum Vitae of Principal Investigator	1	503 k		10/11/18 delete EDIT
assurance-document.rtf	Listing of Data/Specimen Data Points	1	7 M		10/11/18 delete EDIT
	Assurance Document	1	89 k		10/11/18 delete EDIT

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, the 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](#)

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

The screenshot displays 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 menu with options: myHome, Create Project, Search, Reports, Dept Reports, Scheduling, Admin, and Personalize. A search bar with the text '201810003' and a 'Go' button is visible. To the right of the search bar, there are links for 'HRPO Web Site', 'Jonathan Himmel', 'logout', and 'delegate login'. Below the navigation bar, the page title is 'Kidney Project' and the PI is 'Jonathan Himmel'. On the right side, there is a 'Change Form' section with radio buttons for 'Modification/Update Only', 'Continuing Review Only', and 'Both', and a 'Change' button. The main content area is titled 'Modification Index' and 'Continuing Review Index'. It features a 'Back to Project Index' link and a progress bar with steps 1 through 6. Step 1 is highlighted in green. Below the progress bar, there are three myIRB boxes: '1. Protocol', '2. Participants', and '3. Performance Sites', each with a green checkmark. A red circle highlights the 'Review & Submit' button in the top right corner of the main content area. A red arrow points to the right from the '3. Performance Sites' box. At the bottom of the page, there is a copyright notice: '© 2019 The University of Iowa, Washington University in St. Louis \$:39.0' and a timestamp: '05/23/19 03:35:25'.

Once all sections are green, you will be able to click to review and submit button. Selecting this button will bring up a comparison of the previously approved application and the changes you are requesting to make. This section also allows you to enter a comments to the HRPO team such as a specific name and number to contact with questions or other comments that may be helpful in reviewing the modification. After reviewing the changes, click on Submit Form.

- Clinical/participating site
- Coordinating Center
- Central laboratory or laboratory analysis
- Data analysis, statistical analysis or data management



Requested changes show in green.

- Clinical/participating site
- Coordinating Center
- Central laboratory or laboratory analysis
- Data analysis, statistical analysis or data management

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.)

Please provide the name and phone number of the individual who can best answer questions related to this form submission: This information will help facilitate the review of your form by HRPO staff.

Contact Name:

Contact Phone:

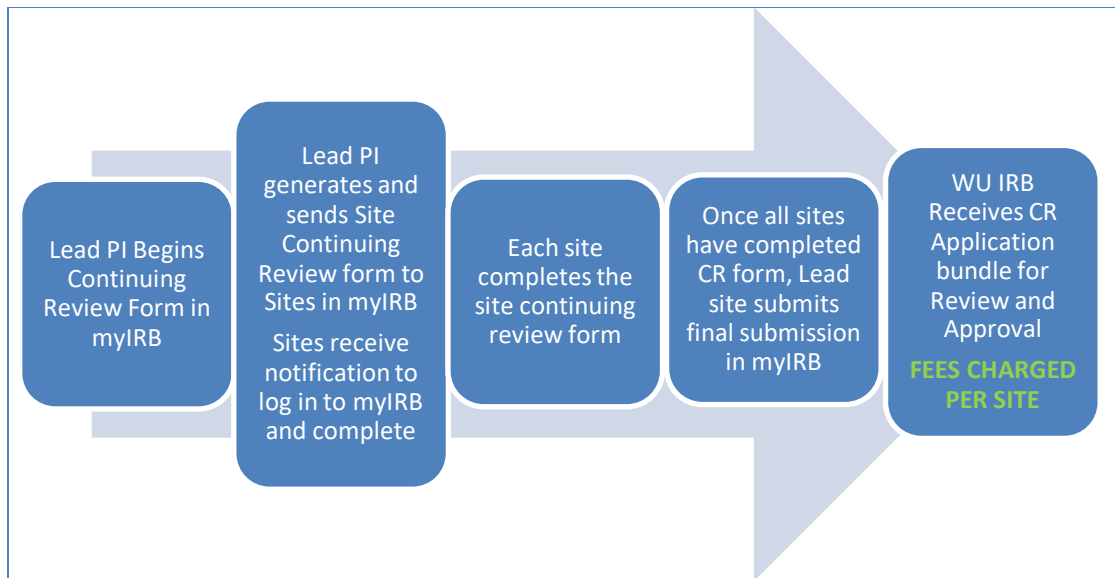
<-- Back/Save

Index/Save

Submit Form -->

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**.

The screenshot shows the myIRB Project Summary page for a Biomedical project (IRB ID # 201907026). The 'Create Form' section is highlighted with a red circle, showing the following options:

- [Continuing Review Form](#)
- [Response Form](#)
- [Project Close Form](#)

The page also displays project details, subjects, FDA information, and federal regulatory oversight options.

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

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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 PI a 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]

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- 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

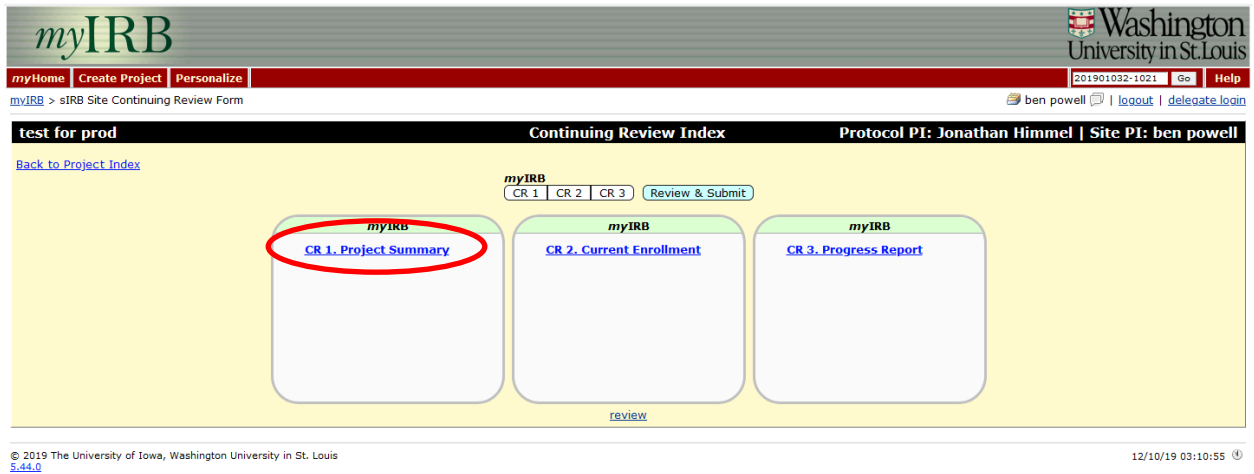
myInbox

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
201801032-102	Regular	sIRB Site CR	BIO test for prod	ben powell	Protocol CR Pre Submit	

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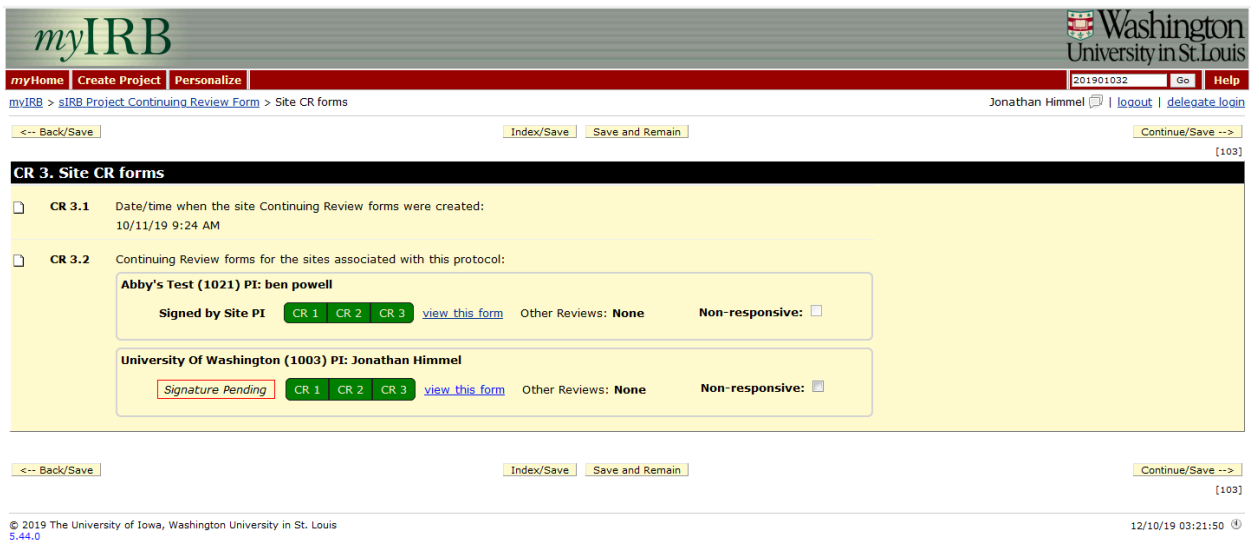
- Click on **CR.1 Project Summary** to open the site specific CR questions and click **Continue/ Save** to save your responses and move forward with the site specific CR

form. You do not need to attach any documents.



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.



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

30

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

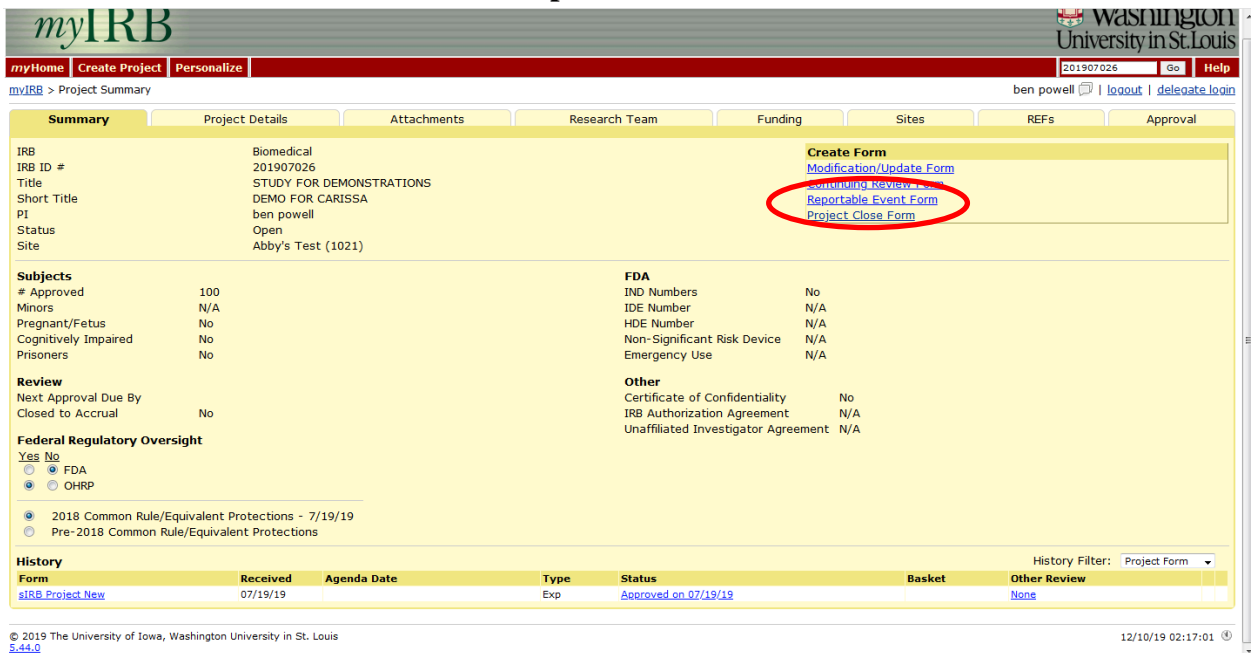
9. The Project CR and all the site forms will be reviewed together and if the CR is approved, the lead PI and their delegates will receive an email from myIRB@wusm.wustl.edu. If there are required actions following the committee meeting, the PI and their delegates will be notified by email.

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 Biomedical project (IRB ID # 201907026). The 'Create Form' section is highlighted with a red circle, and the 'Reportable Event Form' option is circled in red. The page includes sections for Subjects, FDA, Other, Federal Regulatory Oversight, and 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 (IRB ID # 201907026). The page is divided into several sections: Summary, Project Details, Attachments, Research Team, Funding, Sites, REFs, and Approval. The 'Create Form' section is highlighted in yellow and contains links for 'Modification/Update Form', 'Continuing Review Form', 'Renewal/Event Form', and 'Project Closure Form'. The 'Project Closure Form' link is circled in red. Below this section, there are sections for 'Subjects', 'Review', 'Federal Regulatory Oversight', and 'History'.

Form	Received	Agenda Date	Type	Status	Basket	Other Review
sIRB Project New	07/19/19		Exp	Approved on 07/19/19		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.

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 10: 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.