Washington University in St. Louis

WashU | sIRB

myIRB and Single IRB Reference Manual

for

LEAD PIs and Study Teams

Version 2022.11.21

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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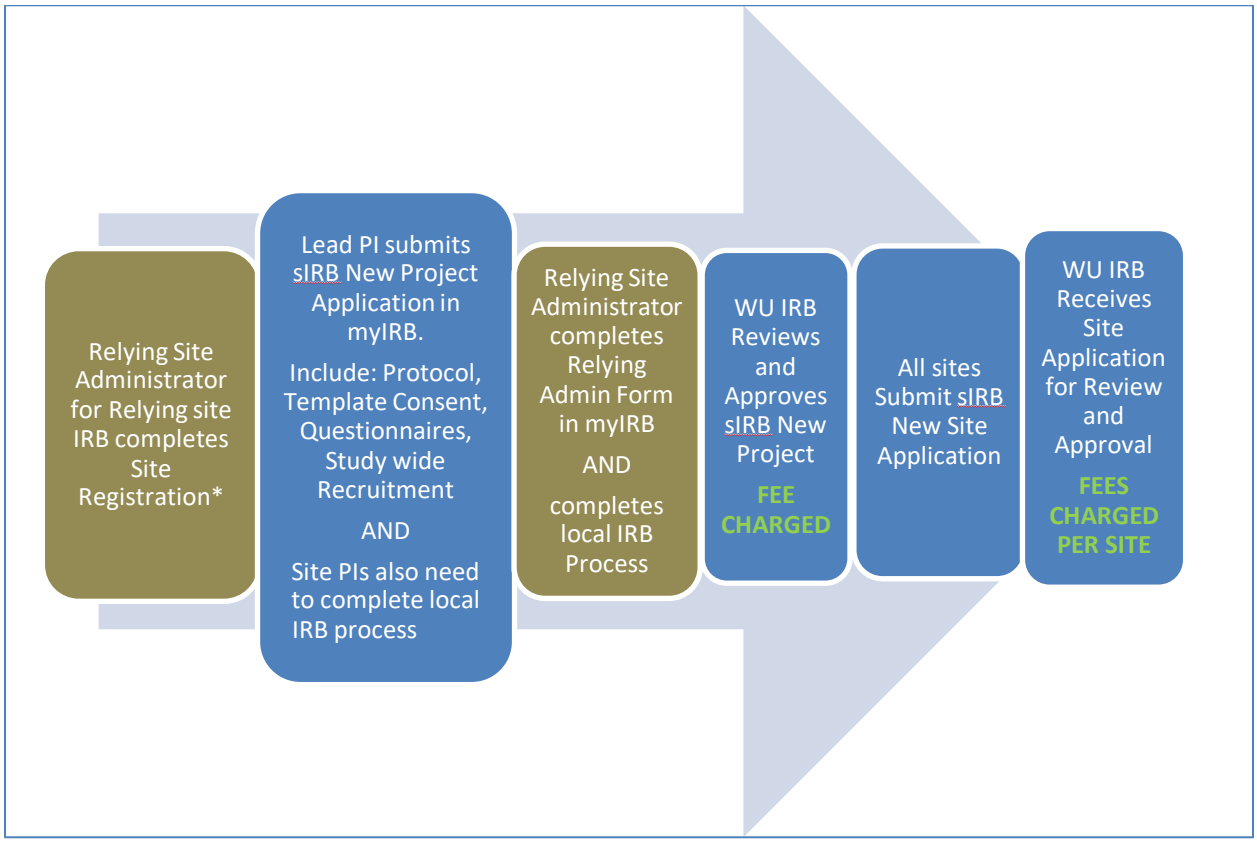
Section 1: Washington University sIRB Review Process



* 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.

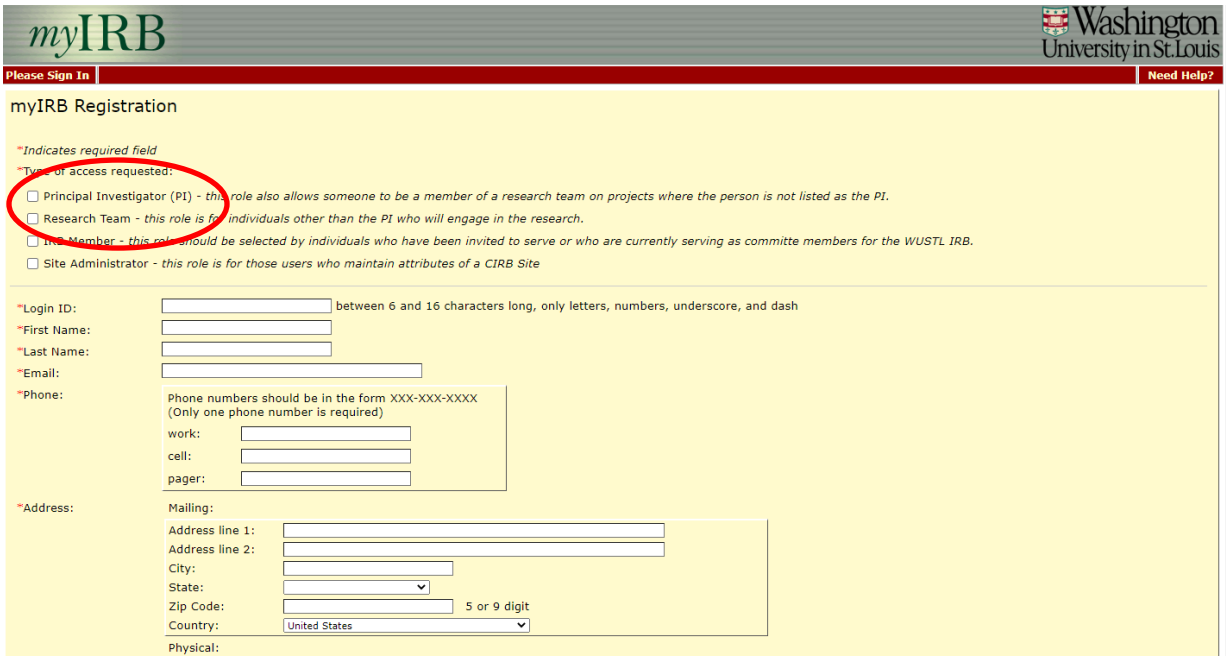
Section 2: Getting Started in myIRB

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.

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.

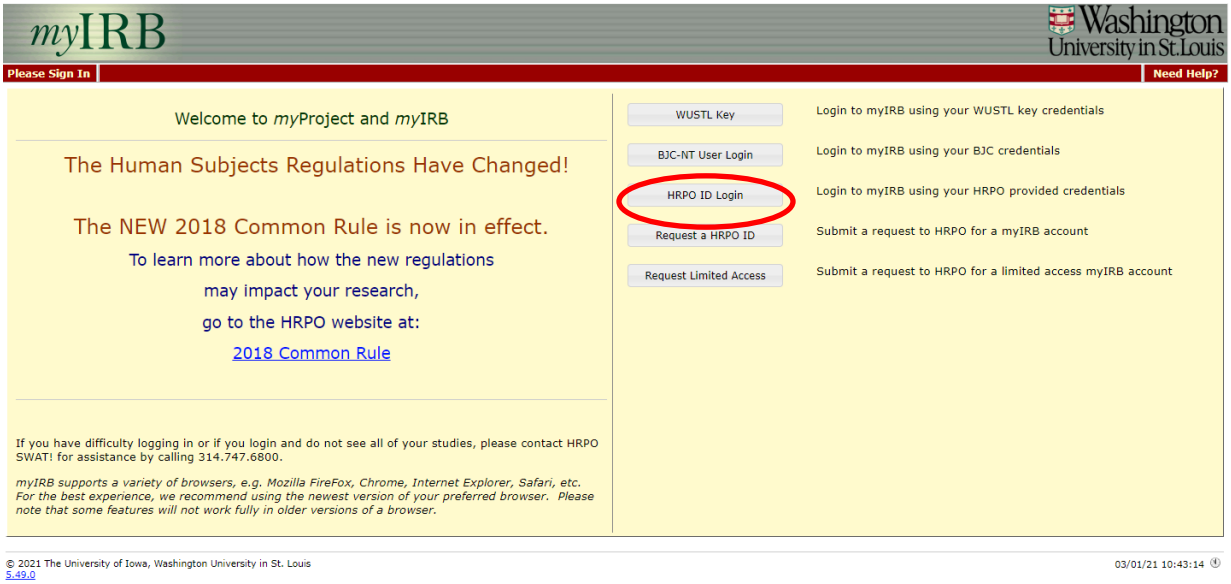
   This email not a monitored account. Do not reply to the email. Please add myIRB@wusm.wustl.edu to your "accepted" email addresses to ensure you can receive emails from myIRB or they may end up in your spam/junk folder. Check your spam/junk mail if the email from myIRB does not arrive within minutes.

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**

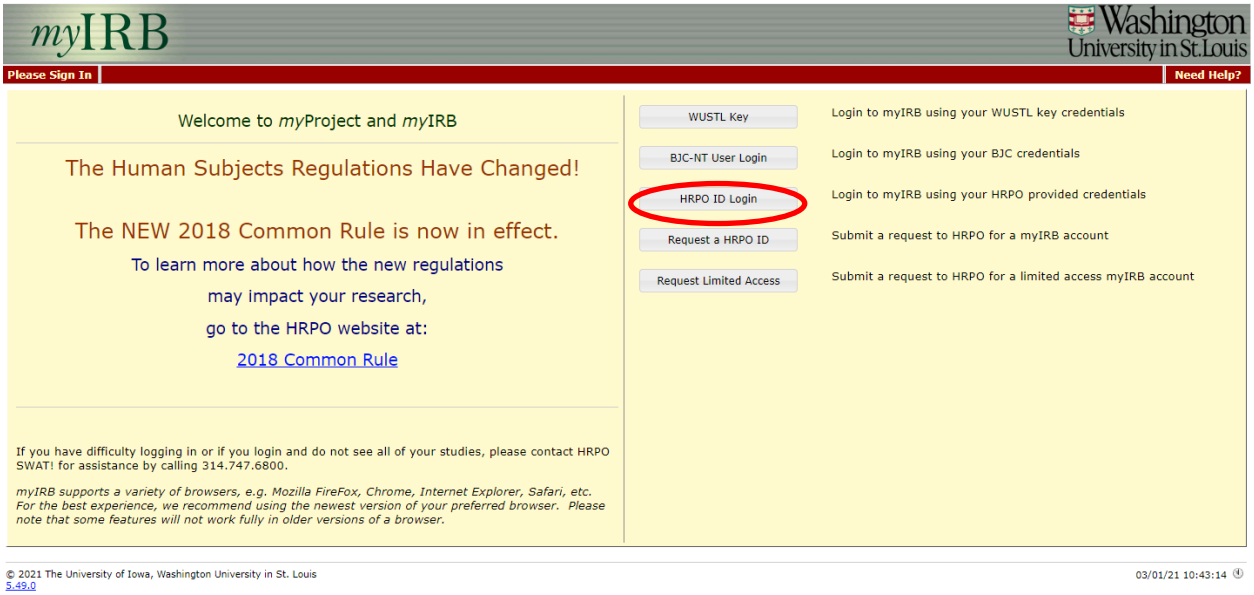


11. The first time you login, review your profile for correctness and click the **Save and Continue** button. Once this is complete, your myIRB **HRPO ID** registration process is complete.

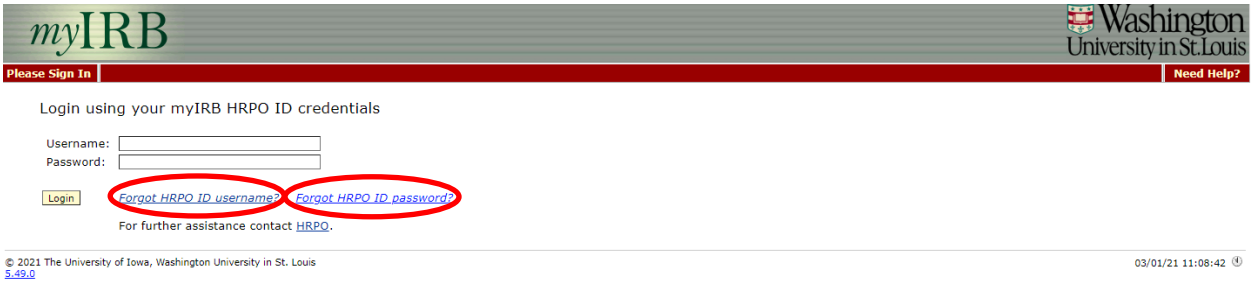
2.2: Logging in to myIRB

1. Go to https://myirb.wusm.wustl.edu

2. Click on **HRPO ID Login**



3. If you have forgotten your HRPO ID or password, click the links under the login credentials fields. After you click continue, you will receive an email from myIRB@wusm.wustl.edu with further instructions.

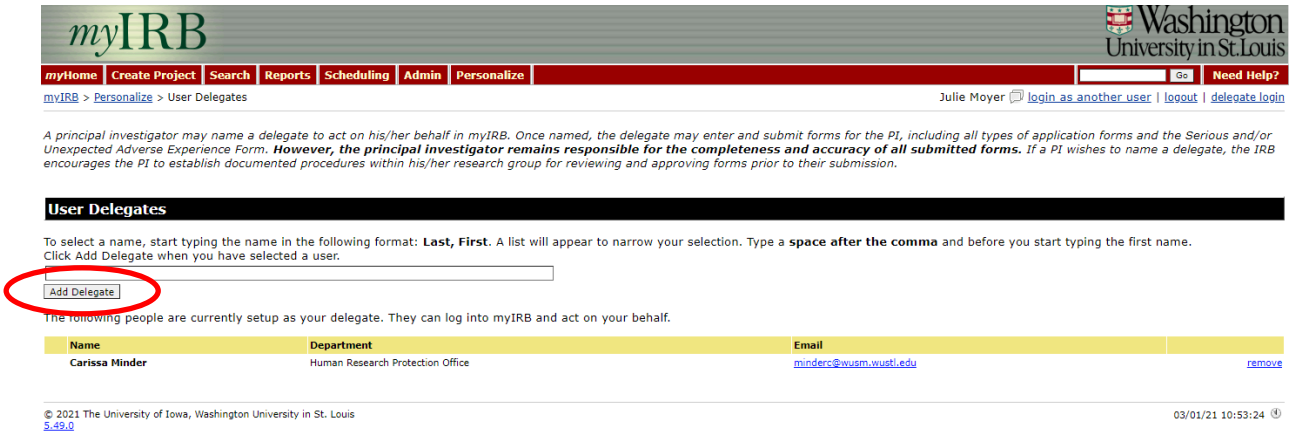


2.3: Delegates to the PI

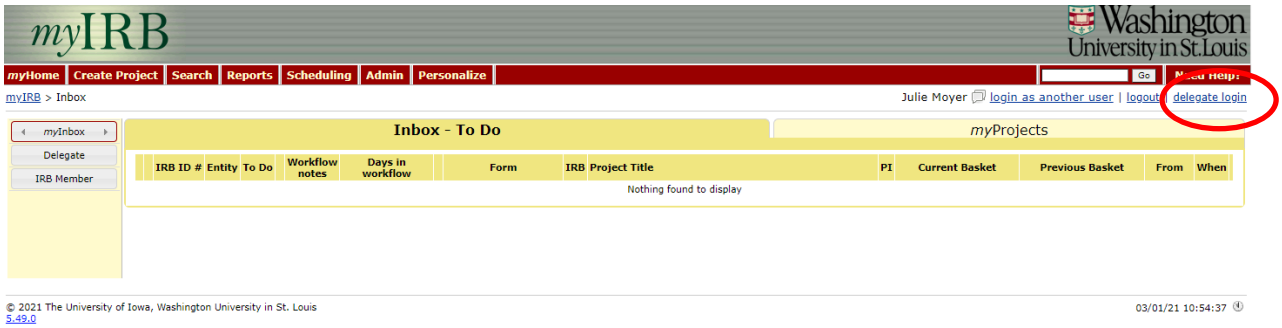
1. If you are a PI and would like to have a study team member complete the myIRB application on your behalf, you will need to name them as your delegate in myIRB.

   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**.

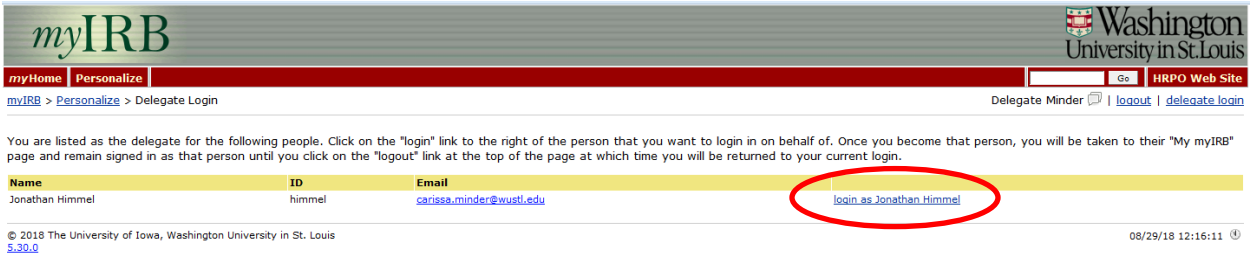
   1) Click on the **Personalize** on the red menu bar at the top of the page.
   2) Click on the gray button that says **Update my delegates**.
   3) Start typing the last name of the person you would like to act as your delegate in the box. When their name appears, select it.
   4) Click the **Add Delegate**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



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.



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



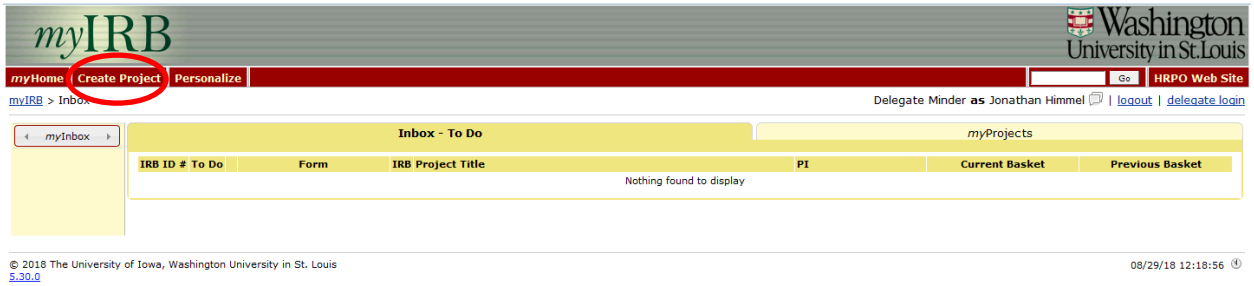
Section 3: New Project Application

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 the study protocol overall.

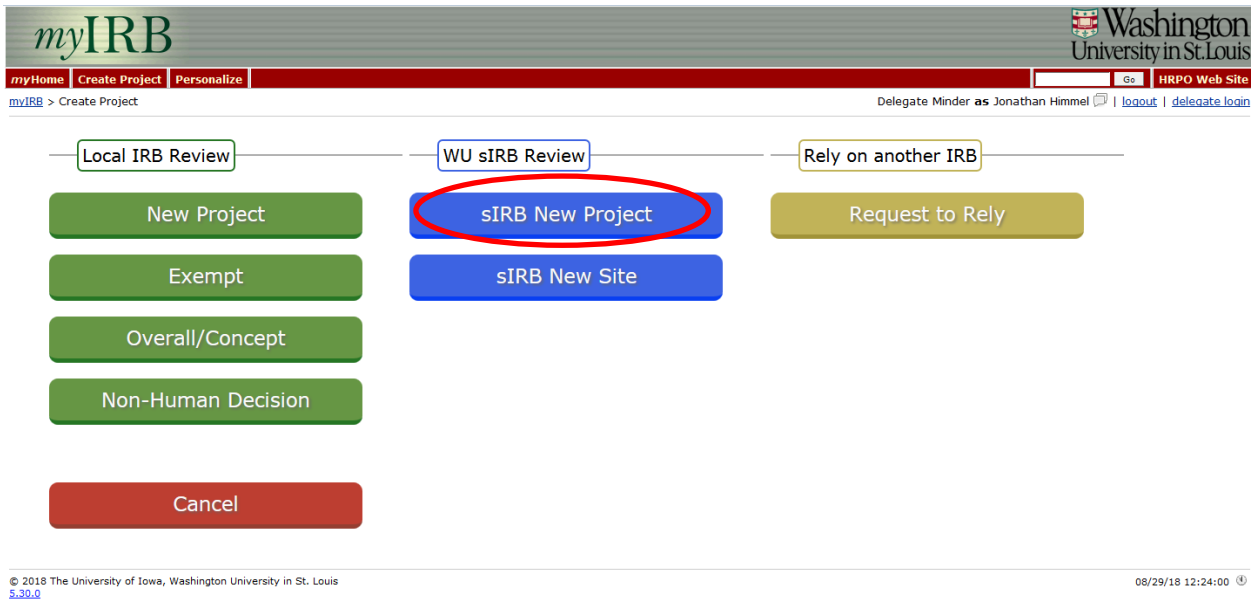
3.1: Completing the New Project Application

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

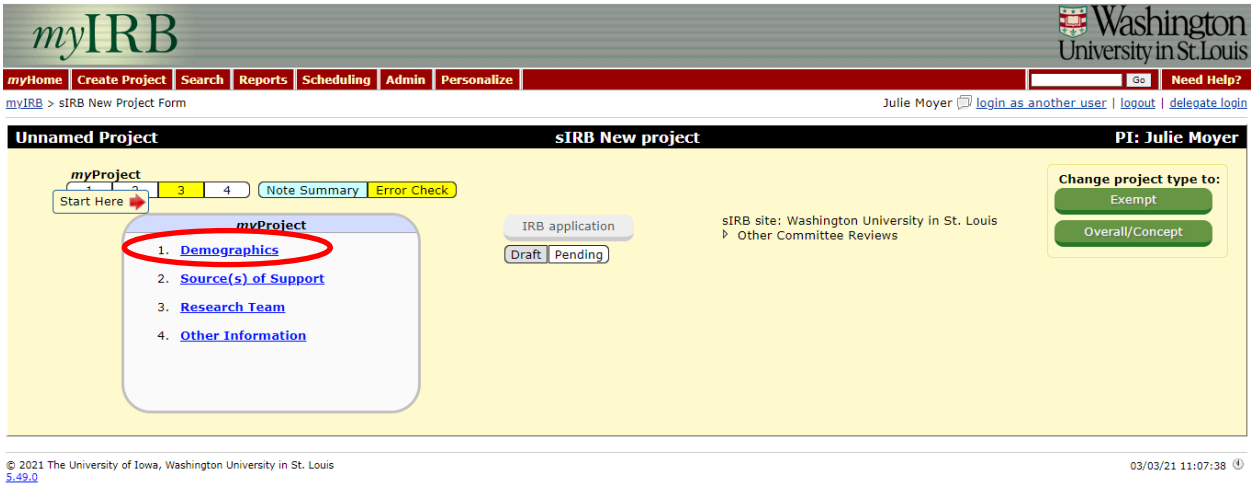
2. Select **Create Project** in the red menu bar at the top of the page.



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



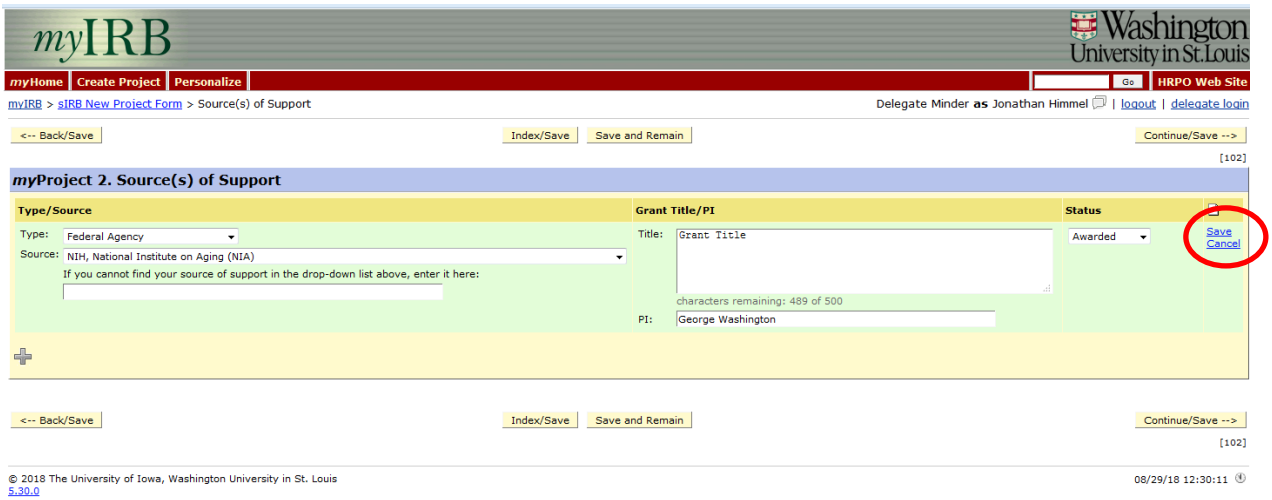
4. You will then enter the electronic application form. To work through the form, start by clicking on the blue **Demographics** link.



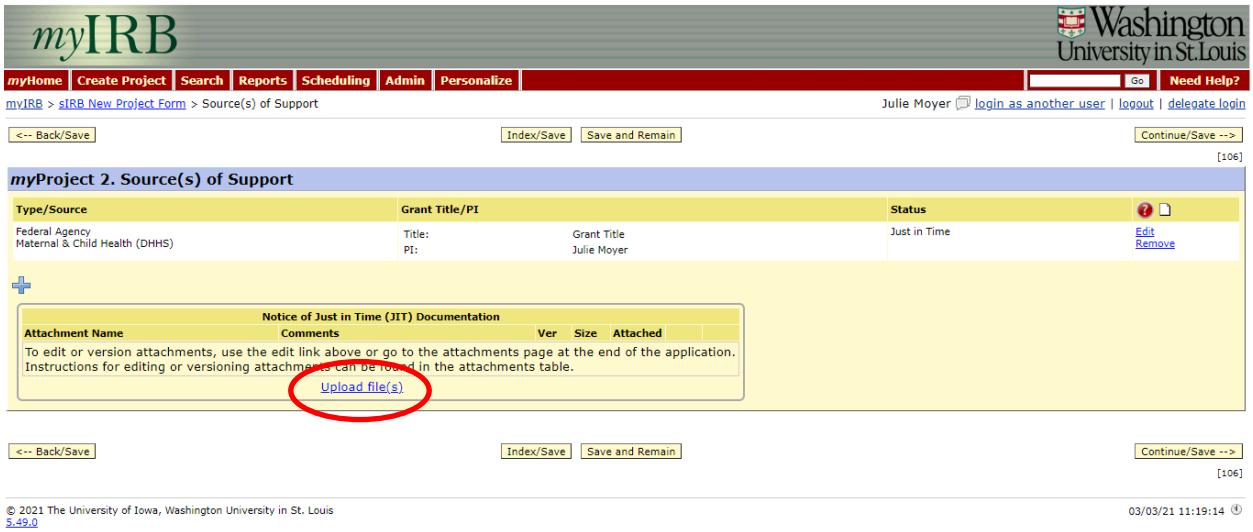
5. You can begin answering questions about the project. The form has smart technology so questions will populate or be suppressed based on the responses to other questions.

   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.

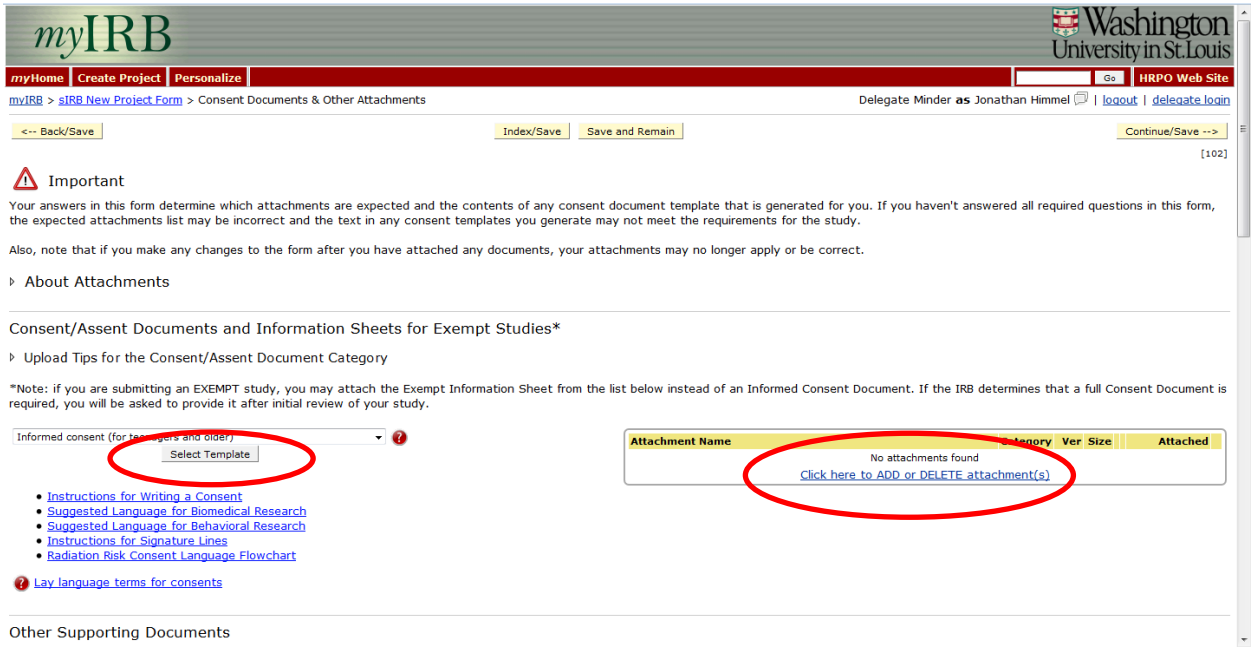


2) Some questions will prompt a place to upload attachments. Click on the **Upload File** link follow the instructions on the pop up to attach your document(s).



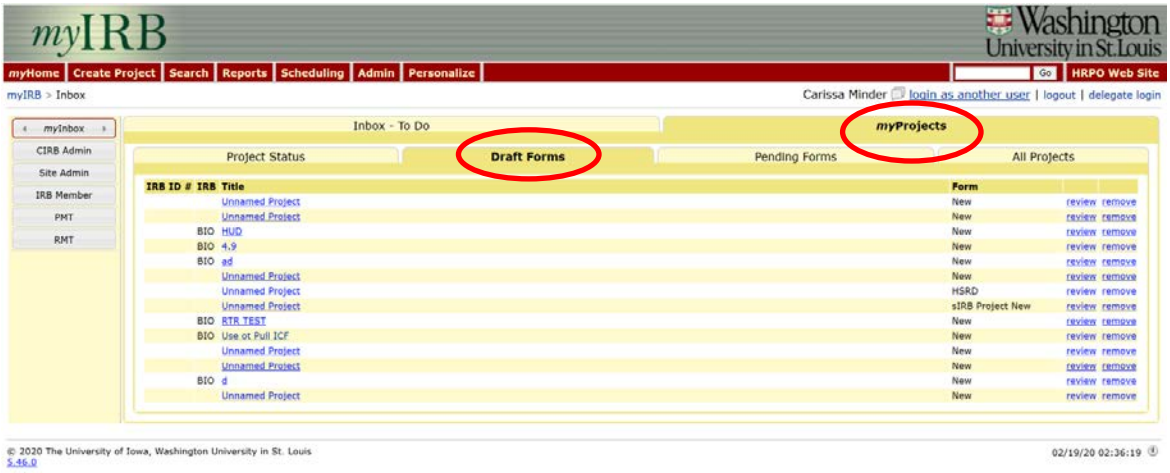
6. You do NOT need to add all research team members in myIRB. Team members are tracked at local sites only. Local processes should be followed to ensure the study team is appropriately trained and qualified.

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.



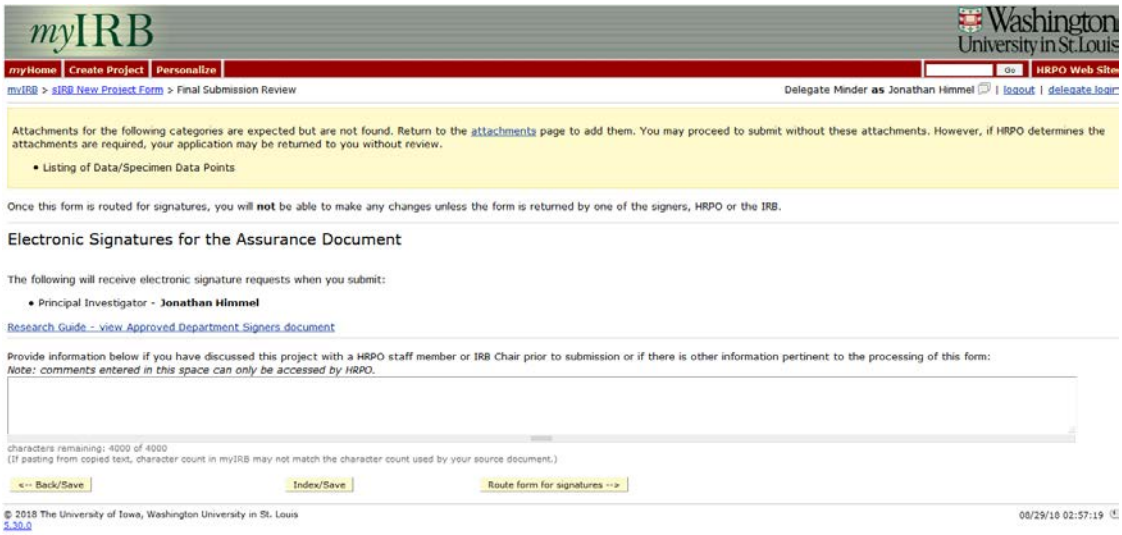
NOTE: Consent files uploaded to myIRB as attachments need to contain a gray IRB stamp box and be in .rtf file format in order to be attached to the application.

8. 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.

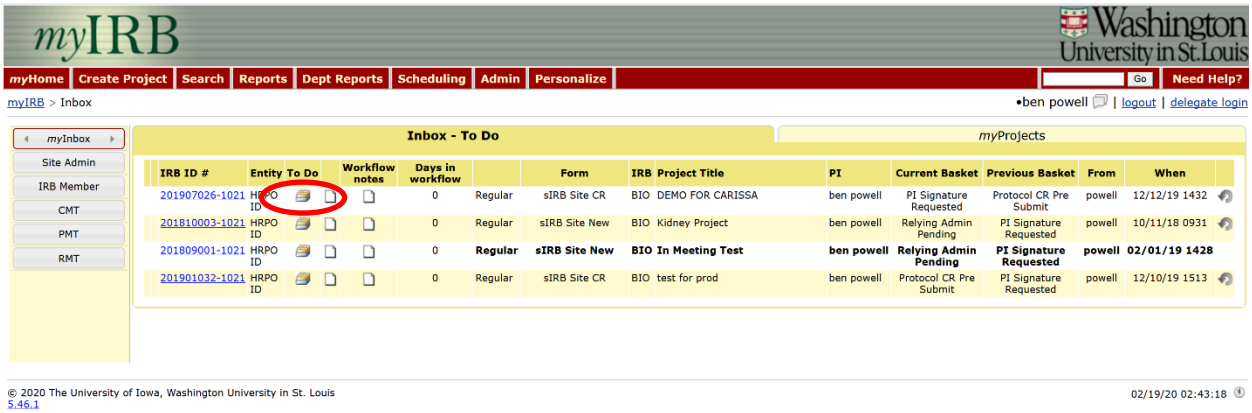


9. When the application is complete, you will be taken to the **Final Submission Review** page. You will be prompted to complete questions and add missing attachments before the form can be submitted. You will see the name and title of the person who will receive the form for Electronic Signatures for 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.



10. 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.



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

08/31/18 11:02:54

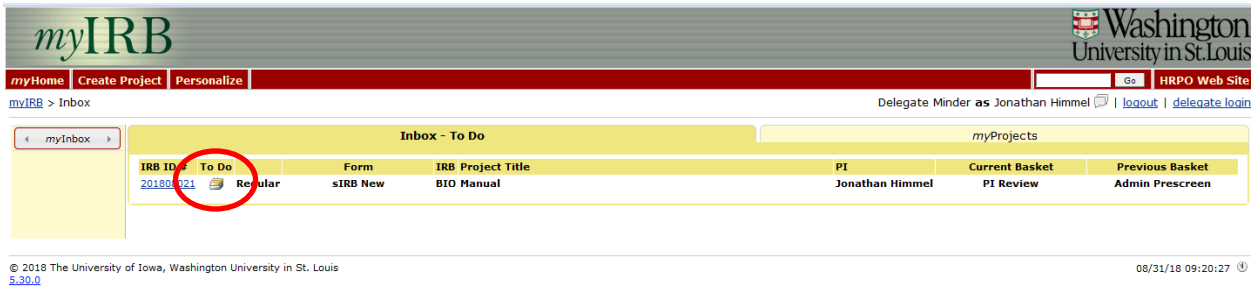
12. At this point, a notice will be sent to your local IRB office administrator letting them know a PI from their institution has submitted a form to the WU sIRB. The local IRB administrator will then log in to the system to assess the information and complete the electronic sign off process to defer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

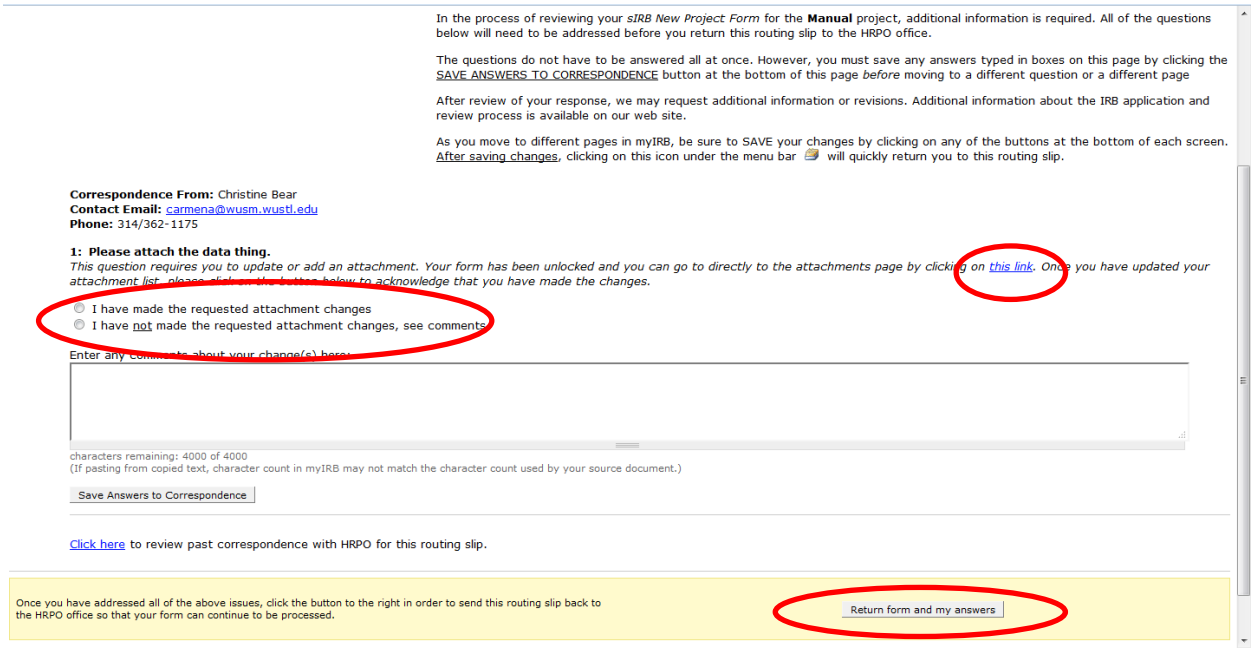
1. If the WU sIRB has questions about your application, you will be contacted through the myIRB system. The PI and their delegates will receive an email from myIRB@wusm.wustl.edu notifying them that there are contingencies to address.

   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.



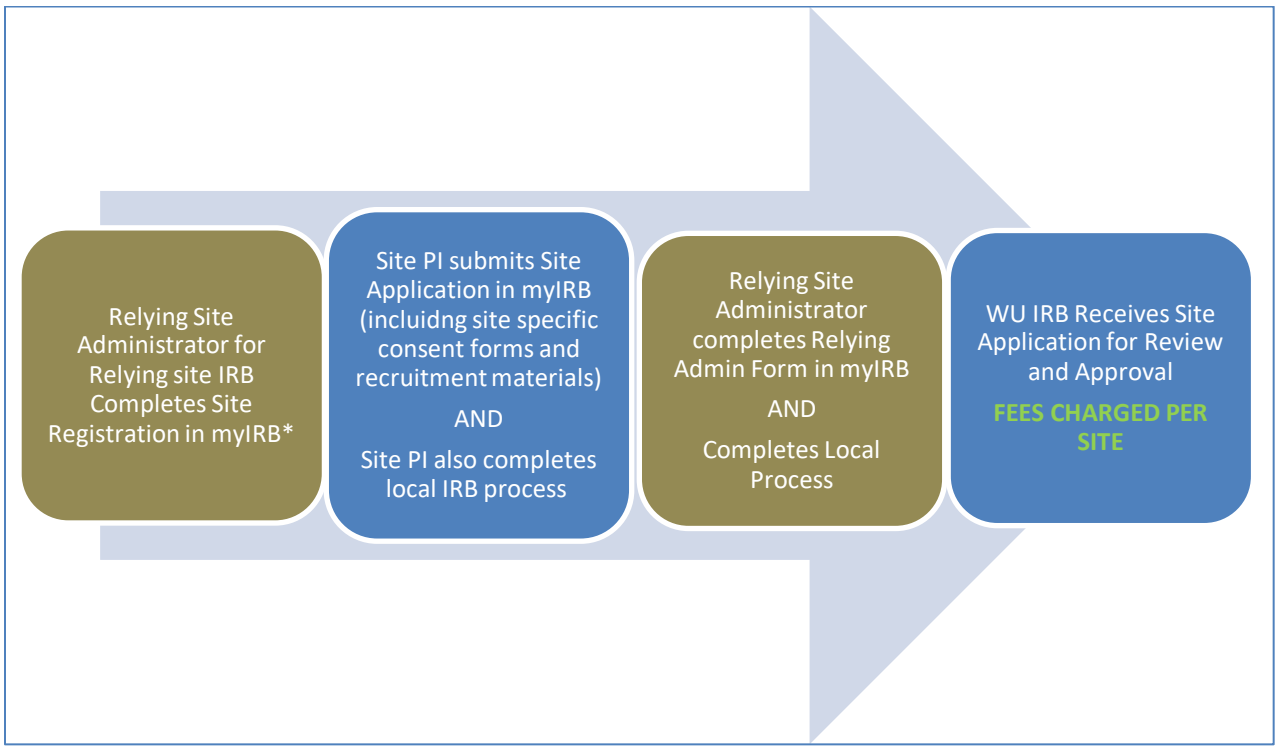
3. You will be directed to the **Workflow** page that will show you what questions or requested changes are being asked of the PI. Click the blue **this link** link to go to the place in the application to address the question or requested changes.



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.



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

4.1: Site Applications

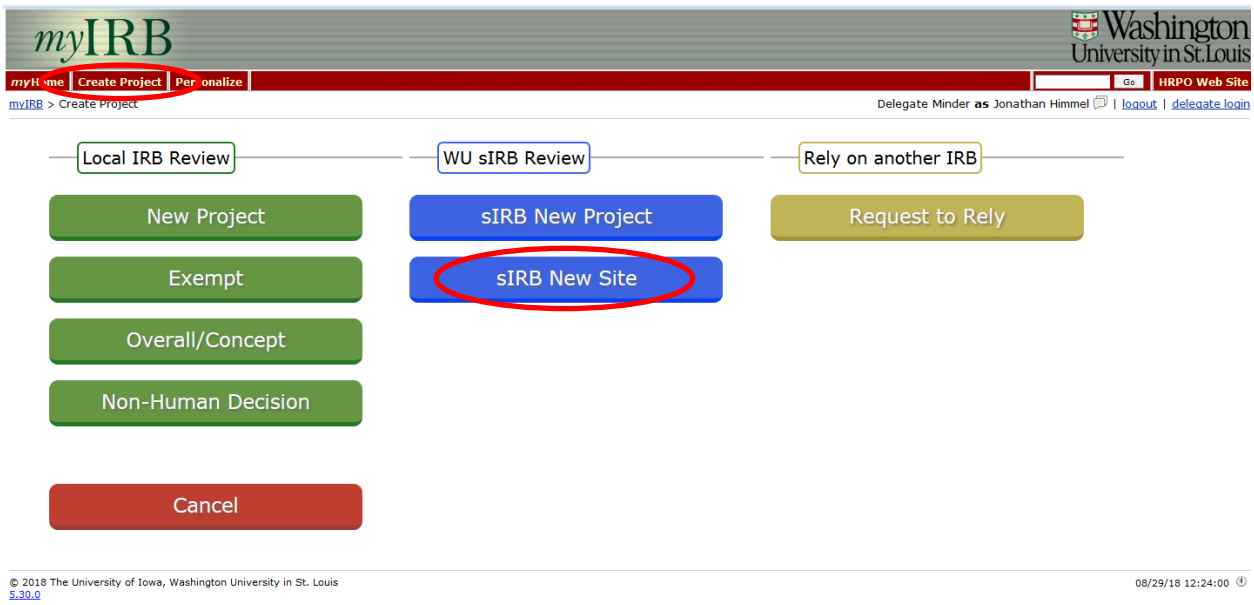
1. All sites, including the lead site, will need to submit an **sIRB New Site** application to obtain approval to conduct the research at their site. Once the **sIRB New Project** is approved by the WU IRB, HRPO will request that the study team provide a list of sites and site contact information using 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

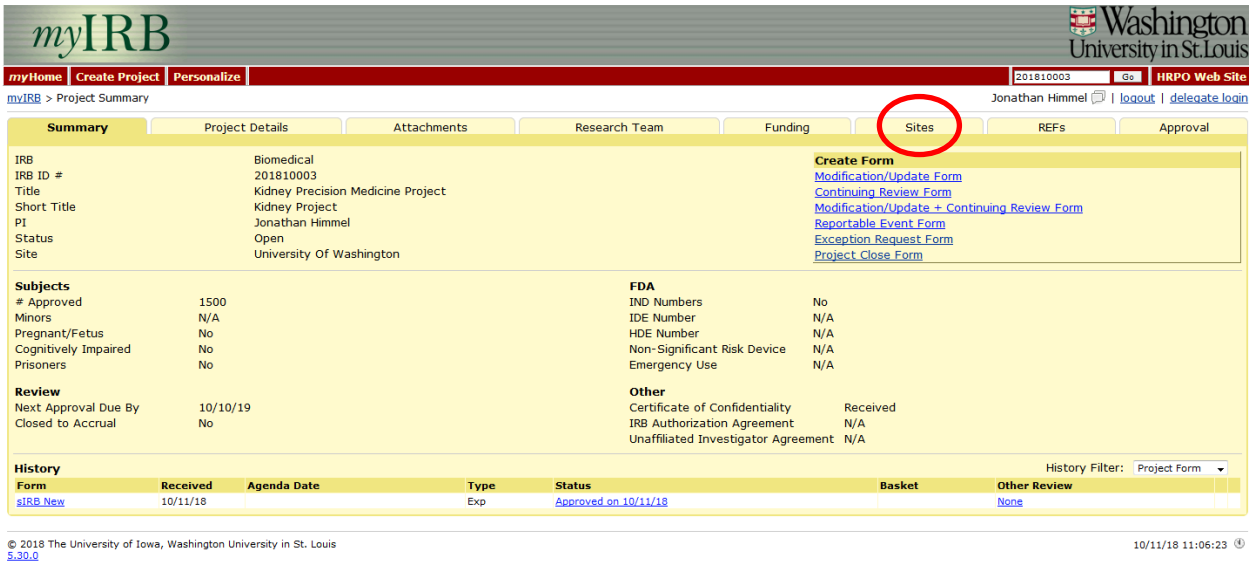
1. To submit a Site Application, log in to myIRB and select **Create Project** then choose **sIRB New Site**.



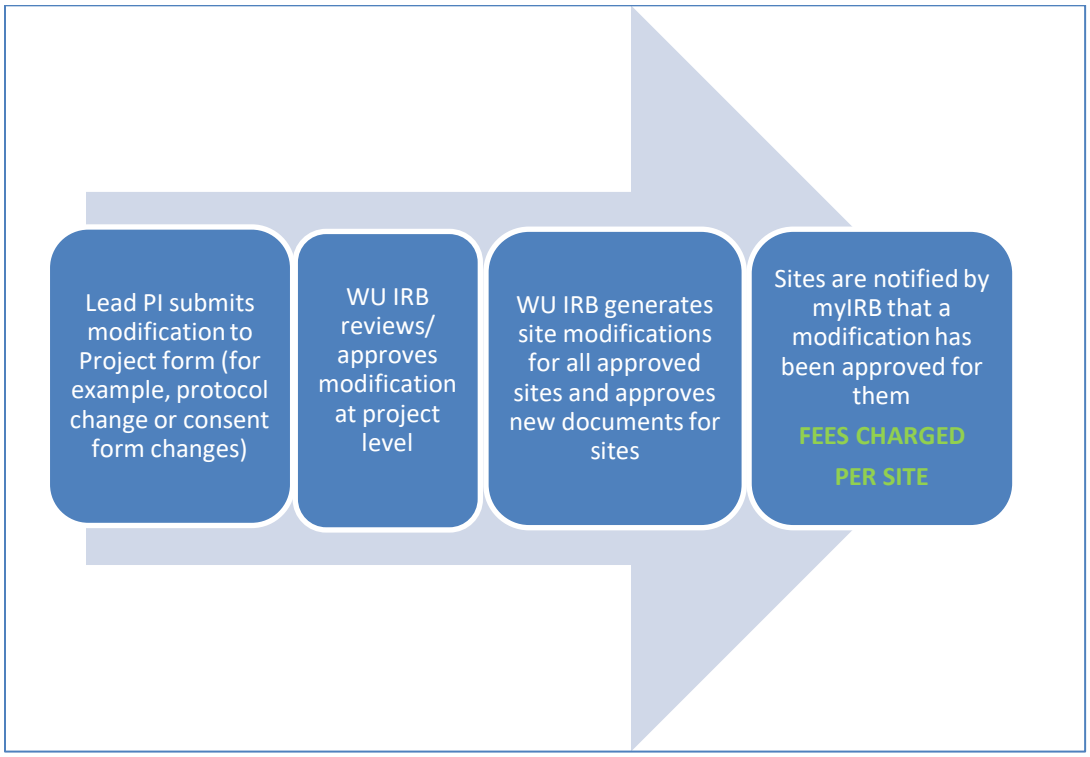
2. You will be prompted to confirm your site PI name and Institution. You will be asked for the IRB ID #.
3. Do NOT attach any questionnaires or study-wide recruitment documents that have already been approved.
4. Do attach any site-specific documents such as recruitment documents.
5. Complete the Site 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.



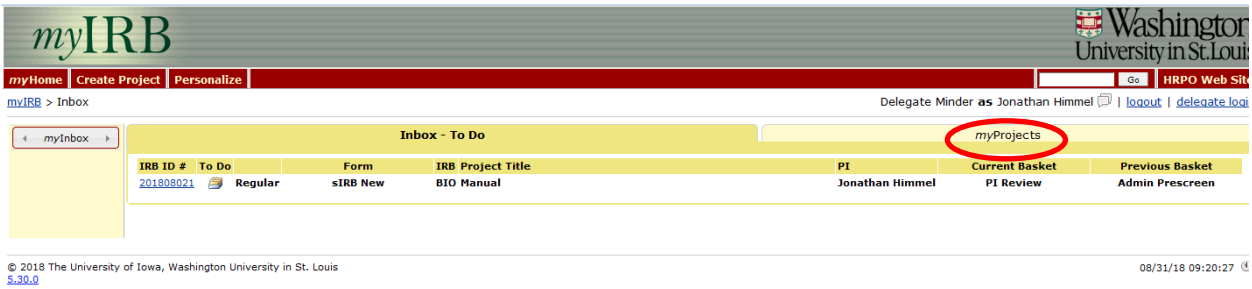
Section 5: sIRB Study Modifications



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.

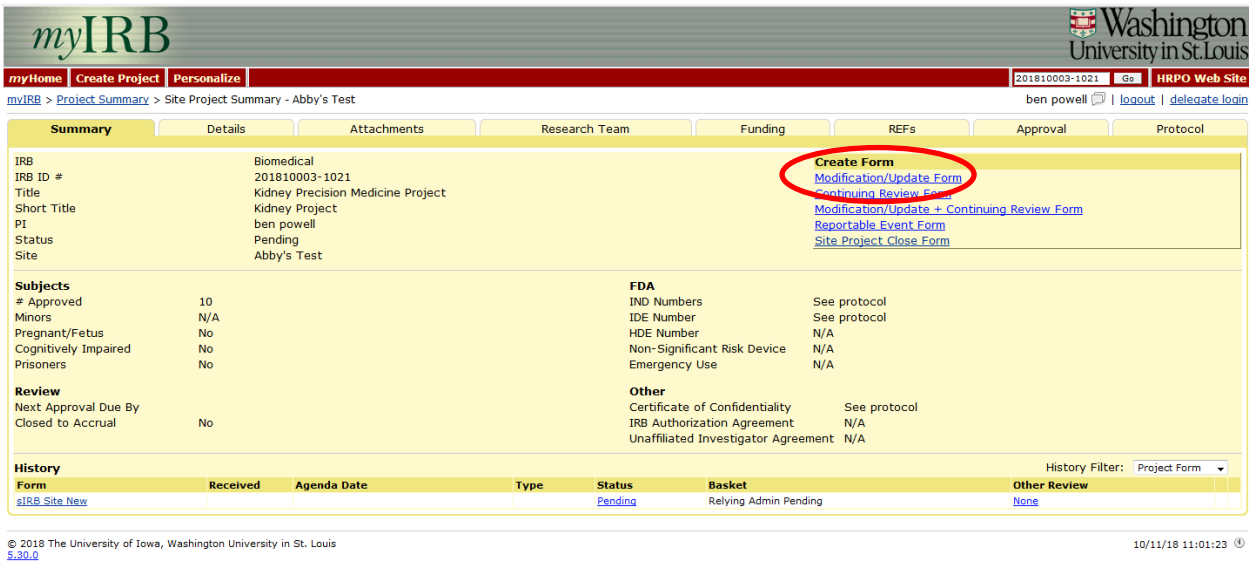
5.1: Submitting a Modification

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

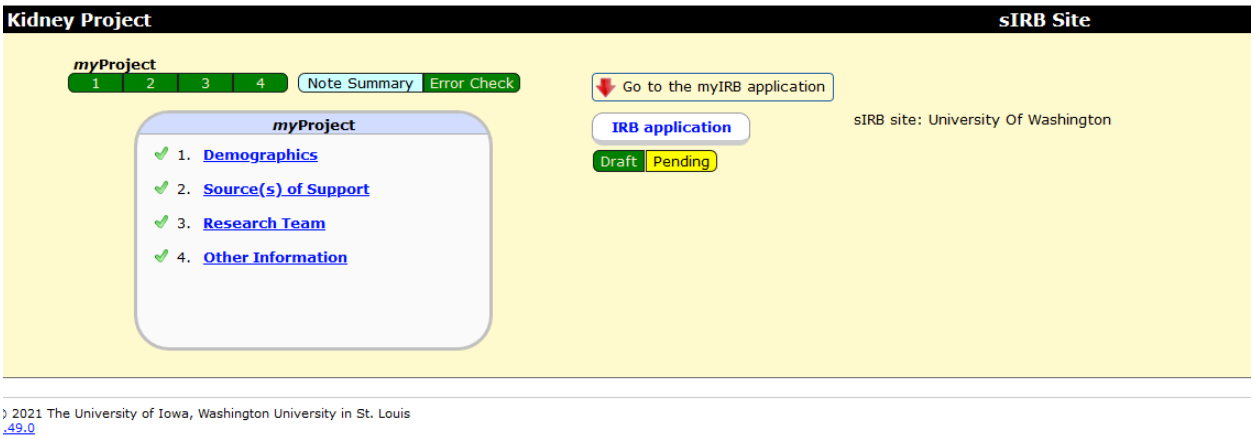


2. Click on **All Projects** and then click on the blue link with the IRB ID #. This will take you to the **Project Summary** page.

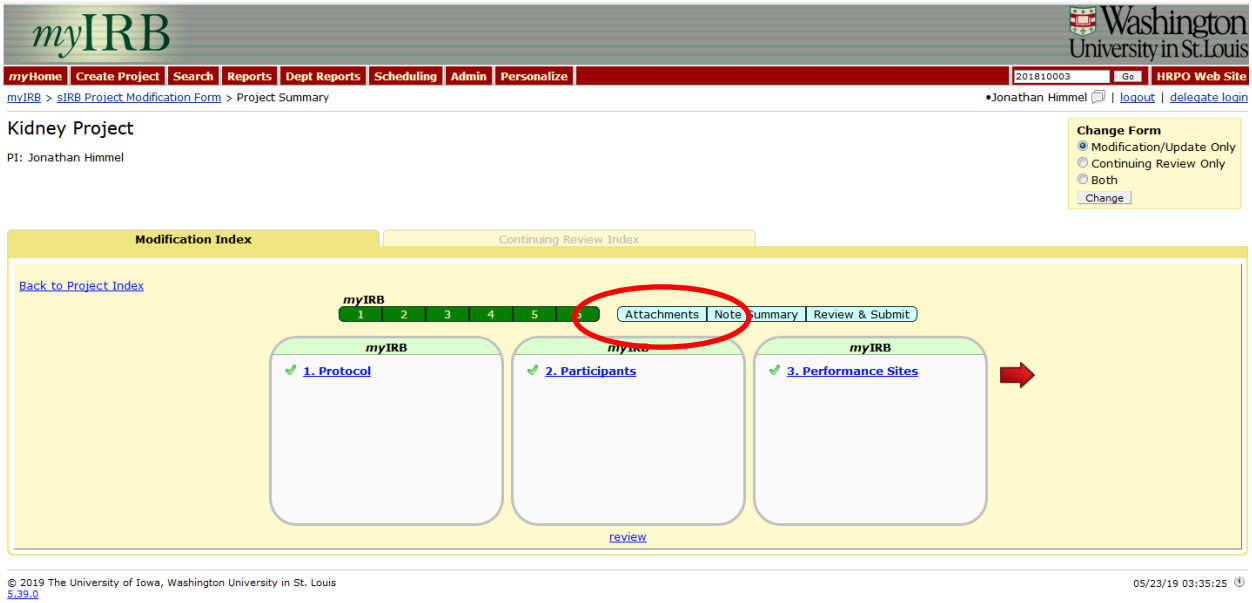
3. Click on **Modification/ Update Form** on the Summary page.



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.

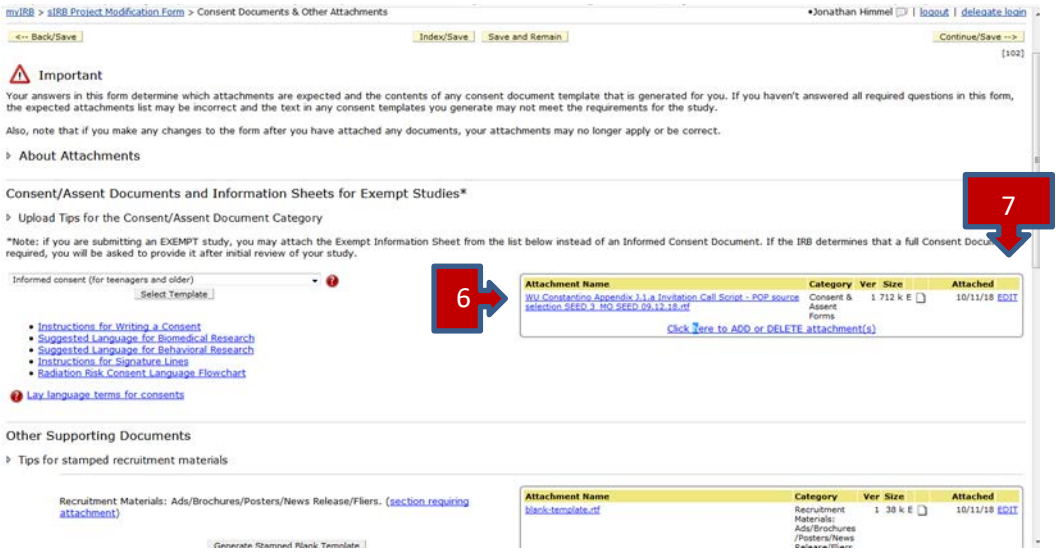


5. To update attachments, navigate to the **Attachments** page by clicking the blue **IRB application** link the middle of the page shown above and then click the blue **Attachments** button.

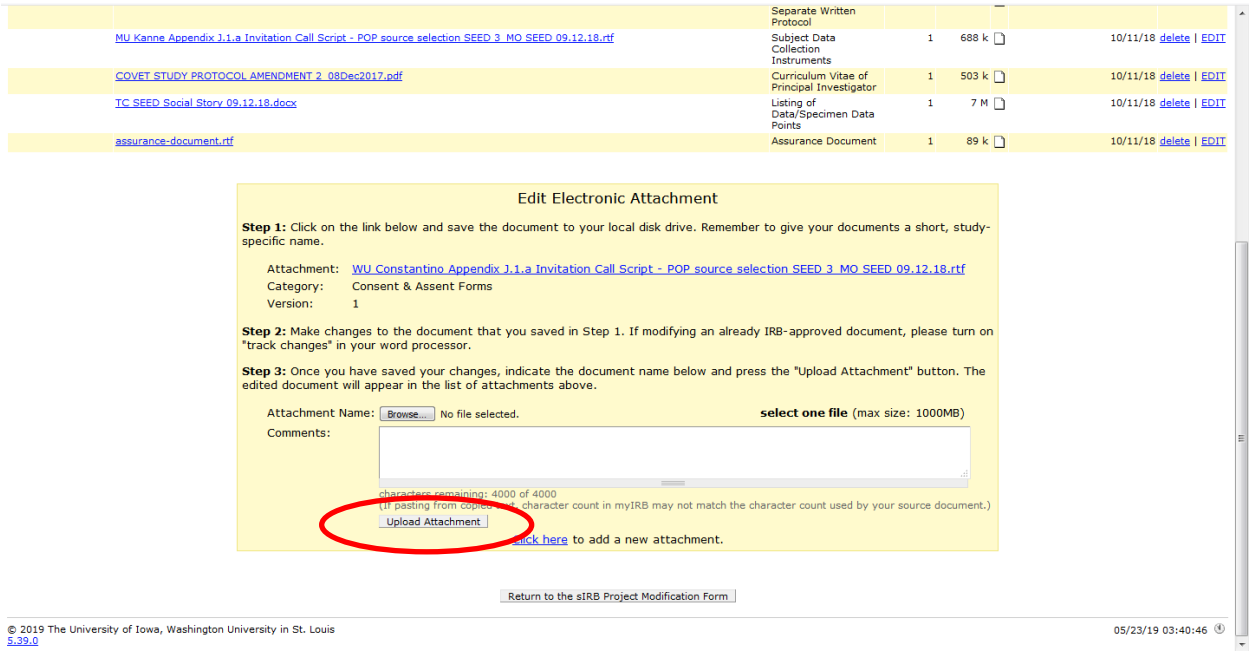


6. When you get to the Attachments page, DO NOT CLICK EDIT! Click on the blue link with the name of the document you want to edit and save a copy to your computer. Make the appropriate edits using TRACKED CHANGES.

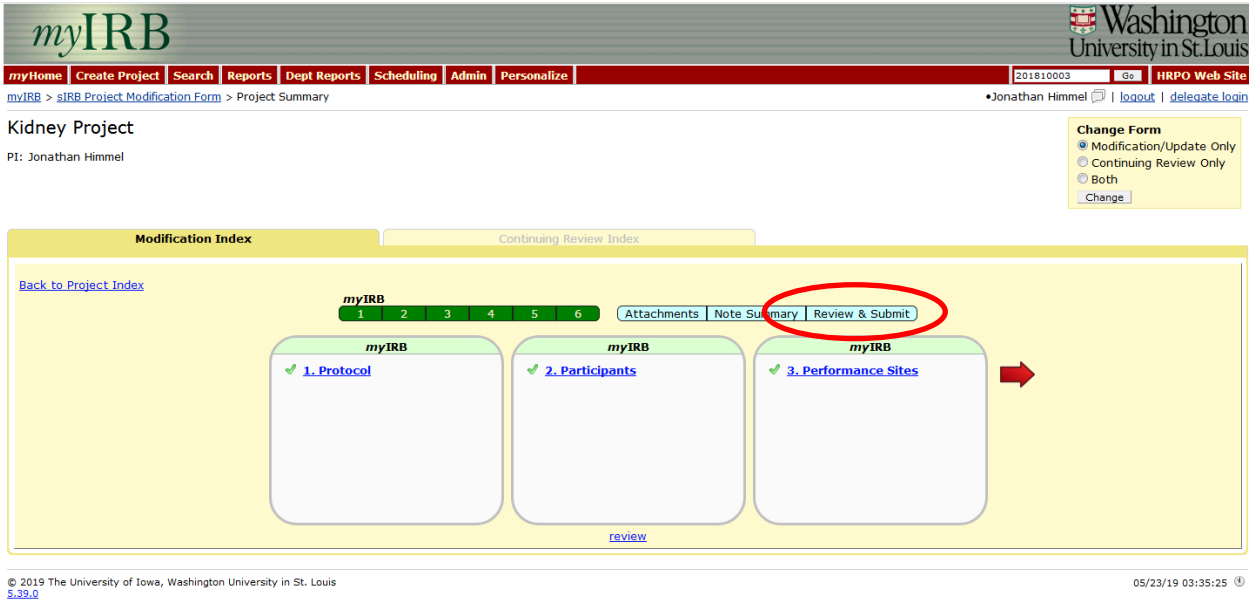
7. Once you have the edited document, click the blue **EDIT** link next to that document.



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



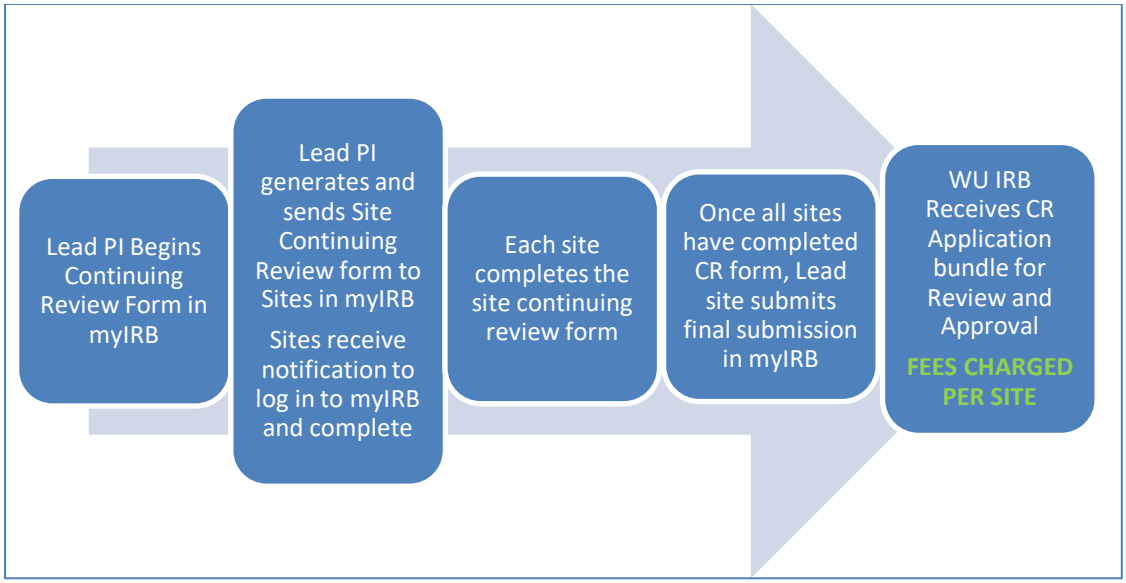
9. Once you have completed your changes, click on the **Review & Submit** button.



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

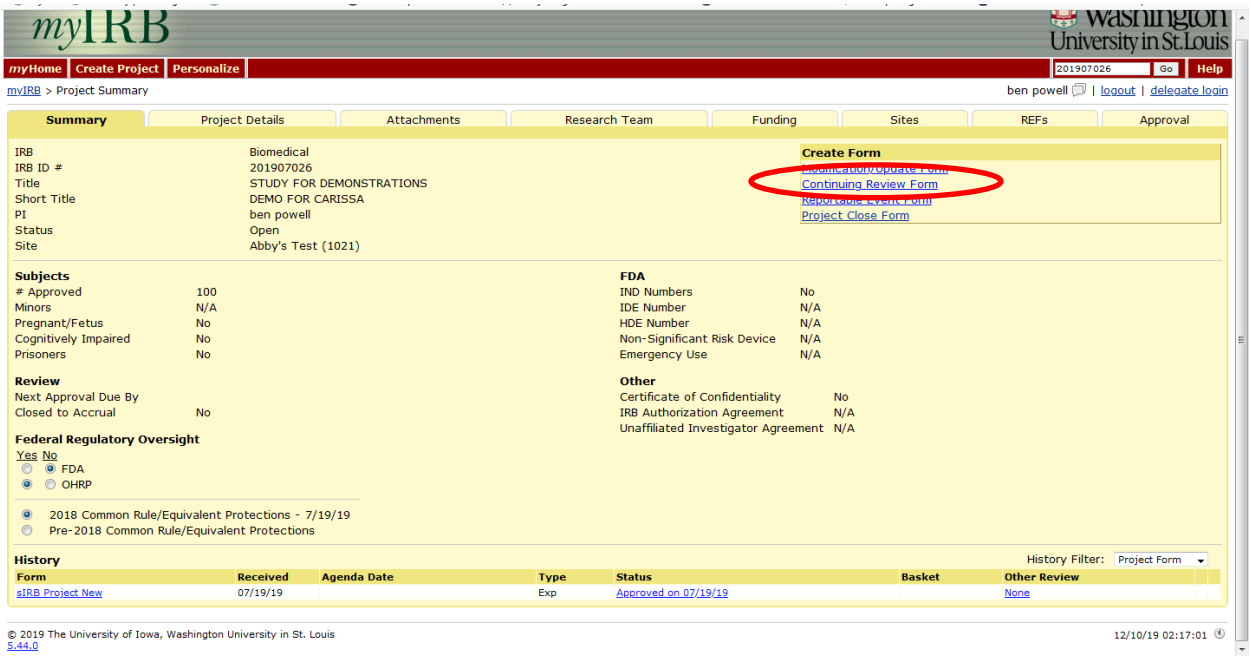


1. The Lead PI will receive a notice when the continuing review of a study is due. The Lead PI will need to log in to myIRB and start the continuing review form.
2. At the end of the form, the Lead PI will click the button generating the site portions of the continuing review forms.
3. The Site PIs will 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

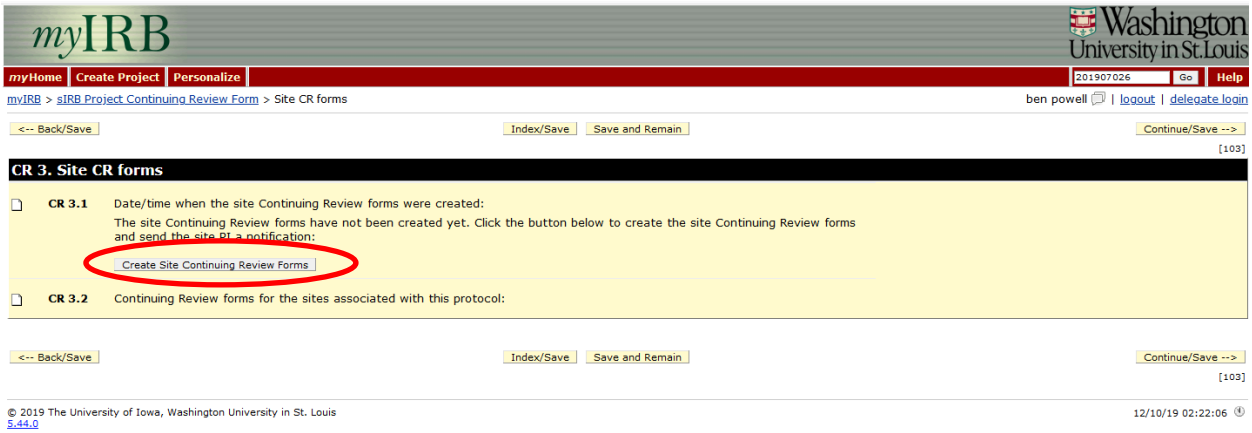
1. After logging in to myIRB, navigate to the **myProjects** tab and then the **All Projects** tab. Click on the IRB ID # for the study. You will be directed to the Project Summary Page.

2. In the Create Form Box, click on **Continuing Review Form**.



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.

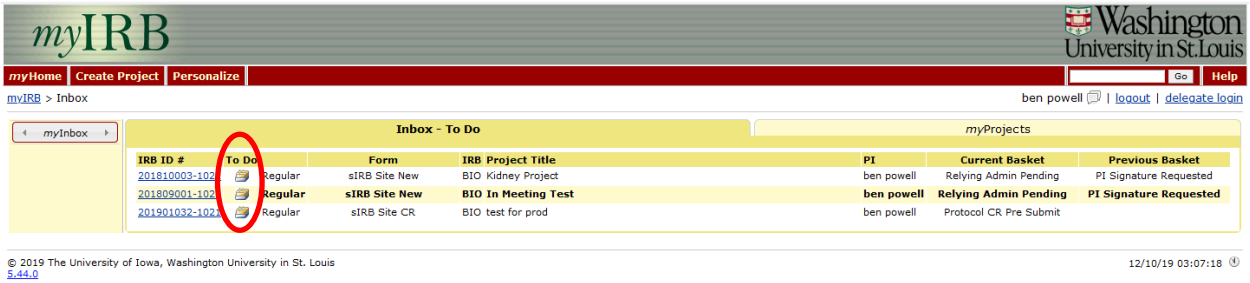
4. When you are ready to send the sites their CR forms to complete, navigate to section **CR 3** and click the gray button that says **Create Site Continuing Review Forms**. The site PIs and delegates will receive an email telling them to log in and answer the questions specific to their site.



5. 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.

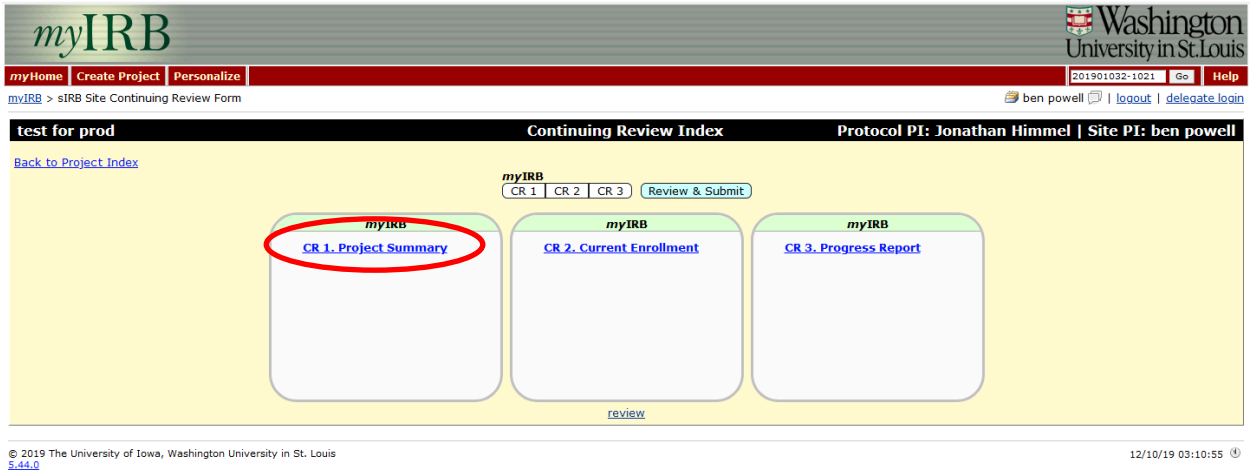
6. You will not be able to submit the form or route the form for signature until all the sites have completed their Site CR form.

   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.



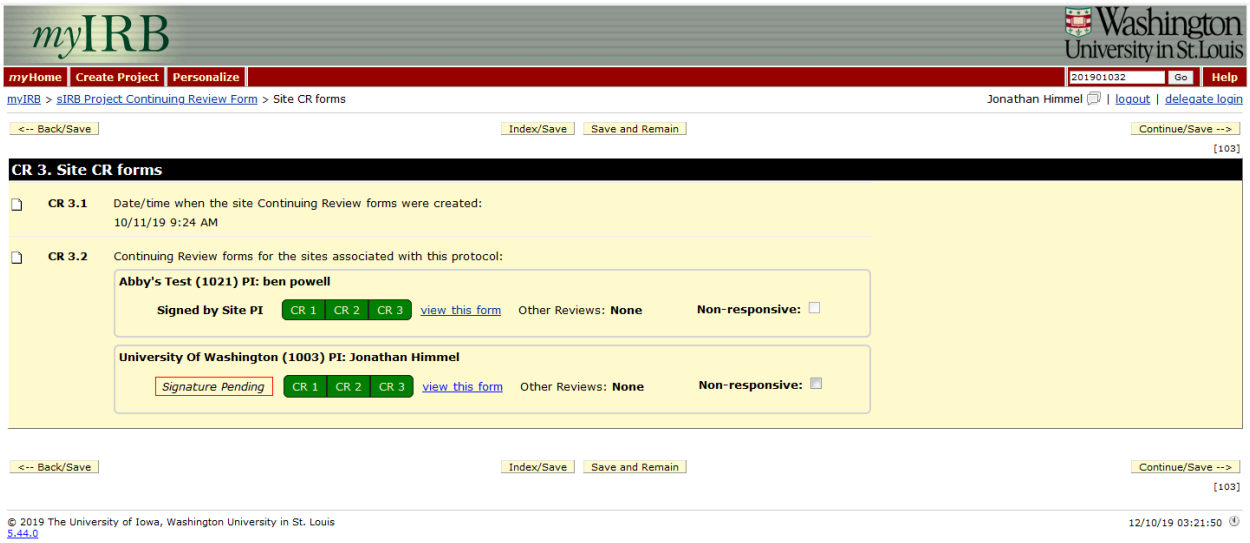
   1) Click **on CR.1 Project Summary** to open the site specific CR questions and click **Continue/ Save** to save your responses and move forward with the site specific CR

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

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.

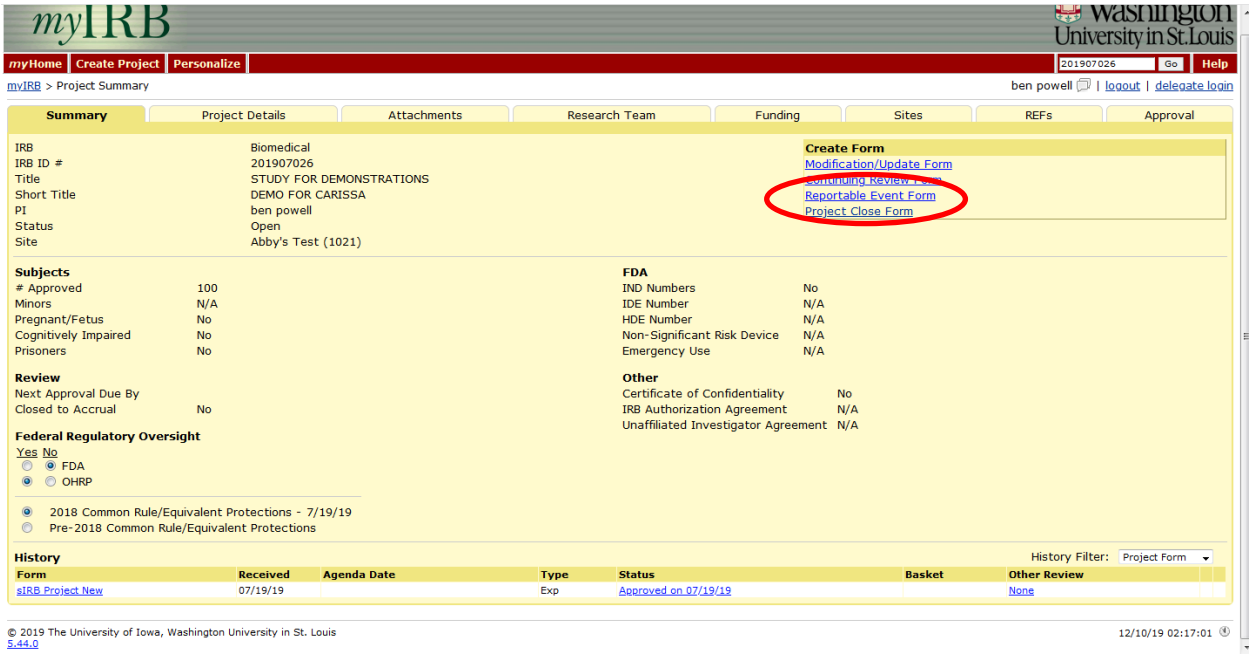
Section 7: sIRB Reportable Events

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**.



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.

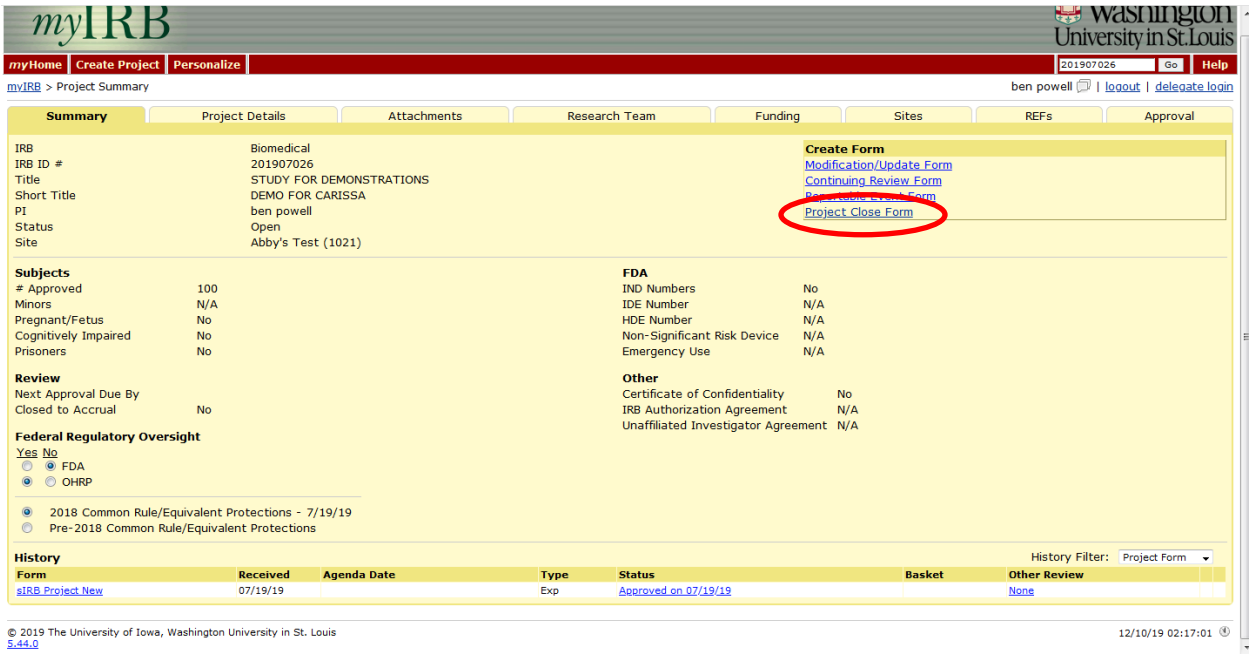
Section 8: sIRB Closure Forms

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**.



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 it not typically on the study team and must be someone with the authority to agree to defer to the WU IRB on a study by study basis.

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

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

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.

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.