Washington University in St. Louis

WashU | sIRB

myIRB Single IRB Reference Manual

for

SITE PIs and Study Teams

Version 2022.11.21

WU Single IRB Contact

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

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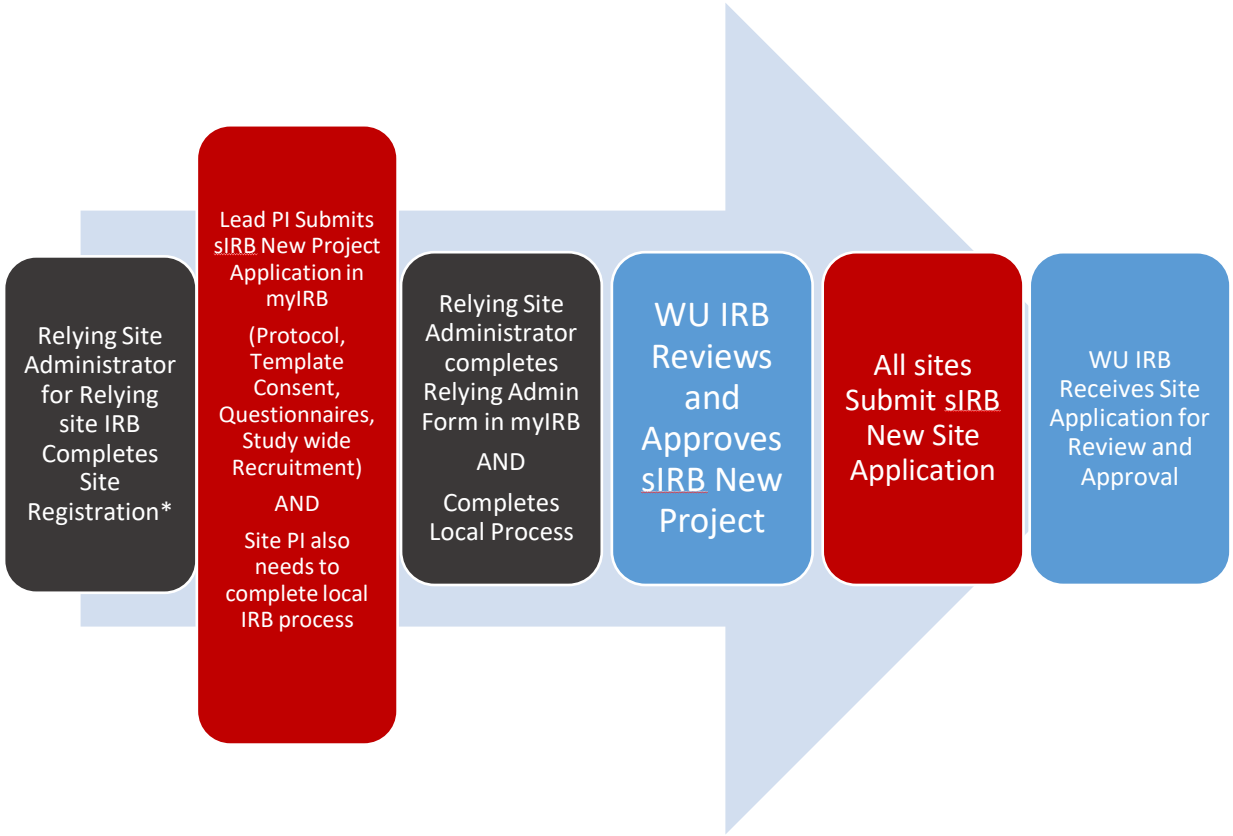


* One Time Process, May Already be completed. WU IRB will provide specific instructions on what steps a Relying Institution Site Administer needs to complete on a study by study basis.

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

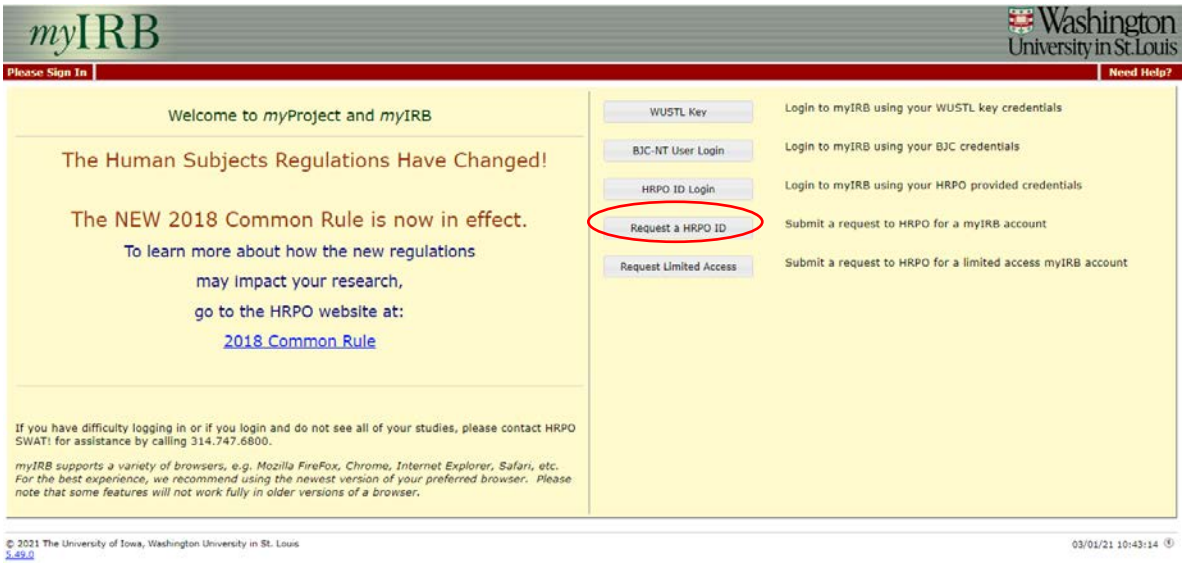
The myIRB system works best when using the latest version of Mozilla Firefox or Google Chrome. Internet Explorer and Safari are not recommended.

Section 2: Getting Started in myIRB

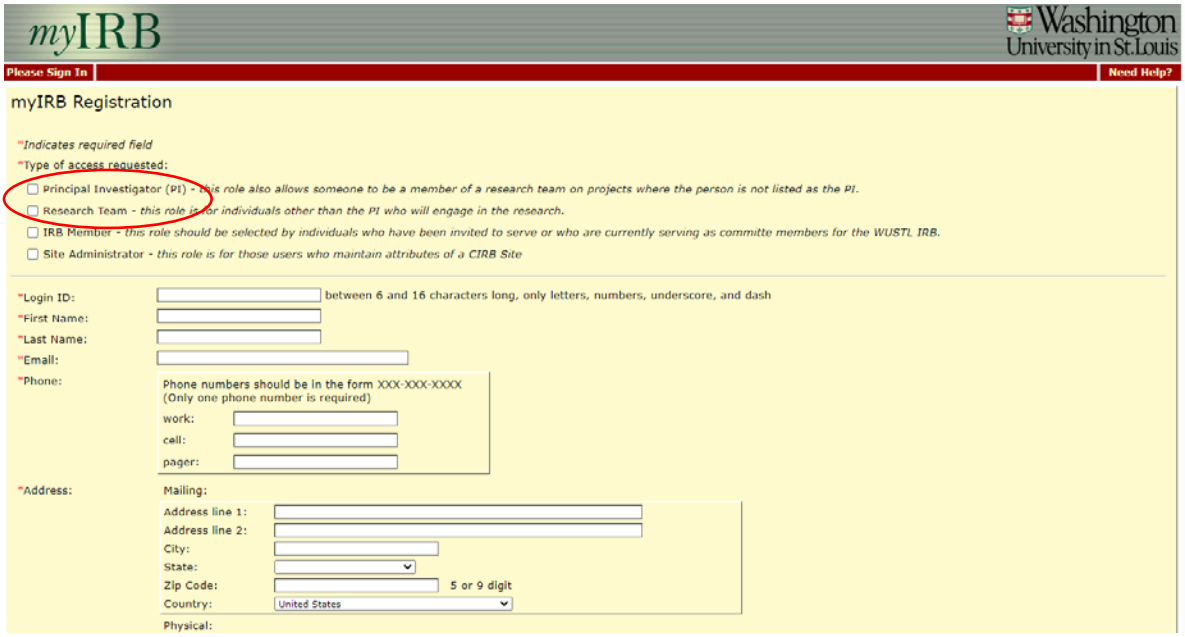
2.1 Request a HRPO ID

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 myIRB Registration is complete, click **Submit Request**.

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

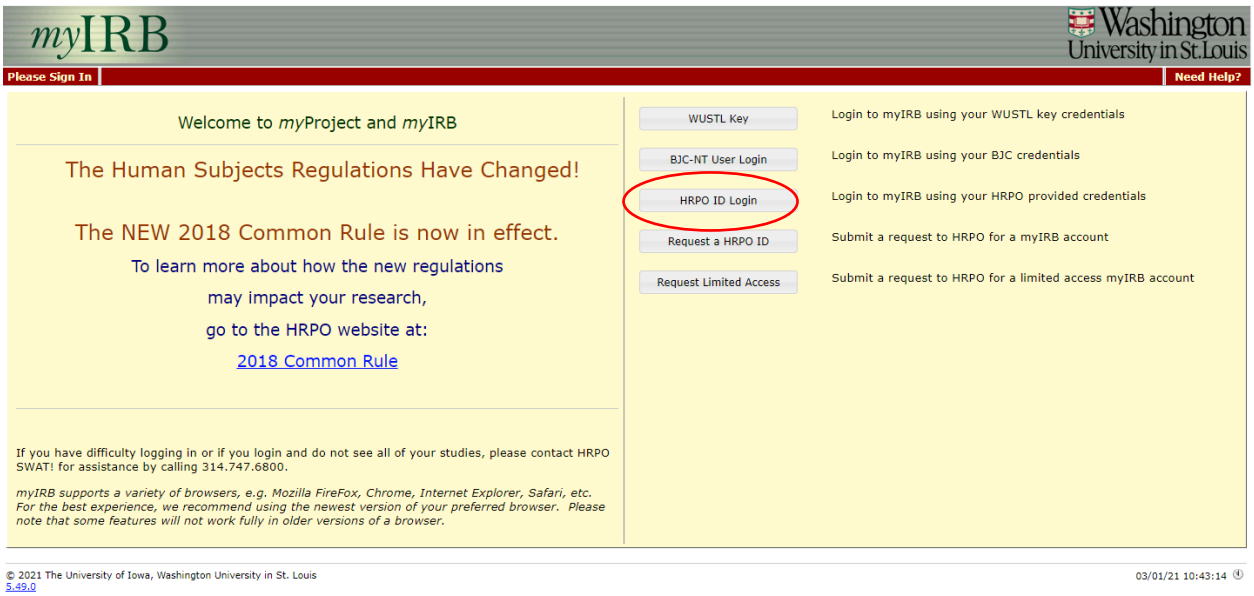
   This email not a monitored account. Do not reply to the email. Please add myIRB@wusm.wustl.edu to your "accepted" email addresses to ensure you can receive emails from myIRB or they may end up in your spam/junk folder. Check your spam/junk mail if the email from myIRB does not arrive within minutes.

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**

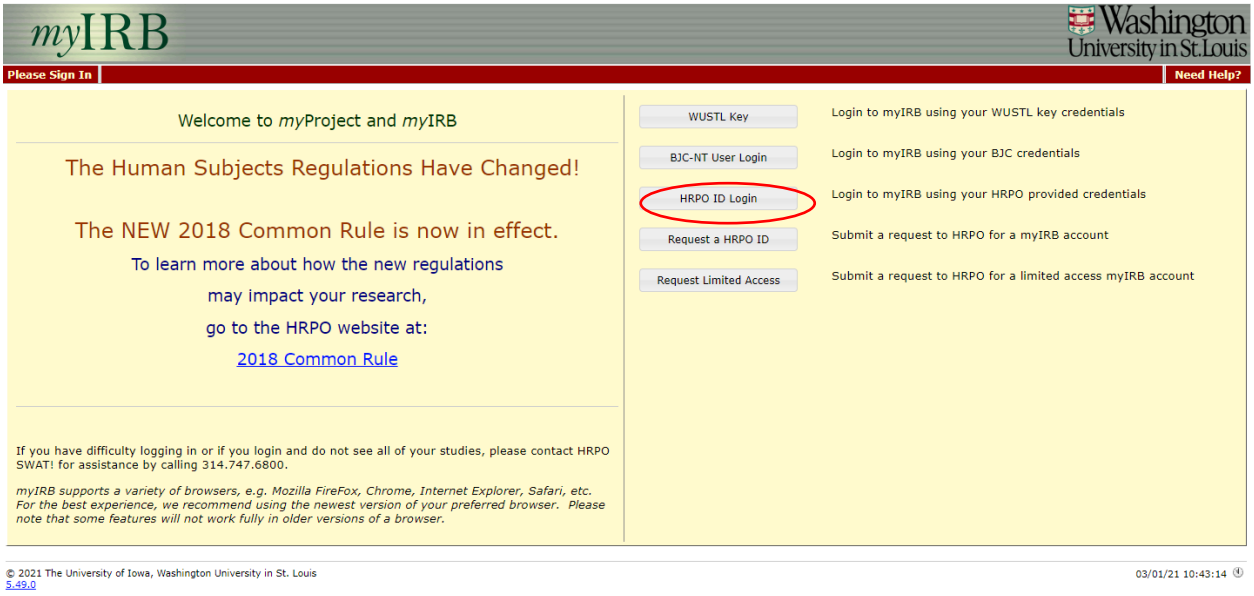


11. The first time you login, review your profile for correctness and click the **Save and Continue** button. Once this is complete, your myIRB **HRPO ID** registration process is complete.

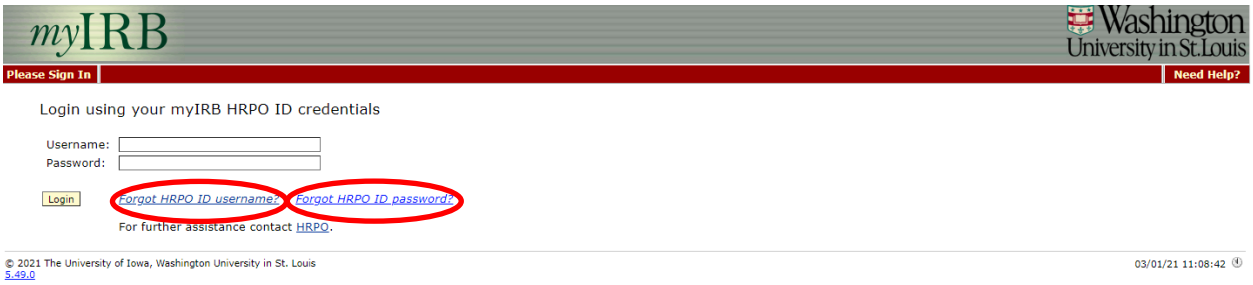
2.2: Logging in to myIRB

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

2. Click on **HRPO ID Login**



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



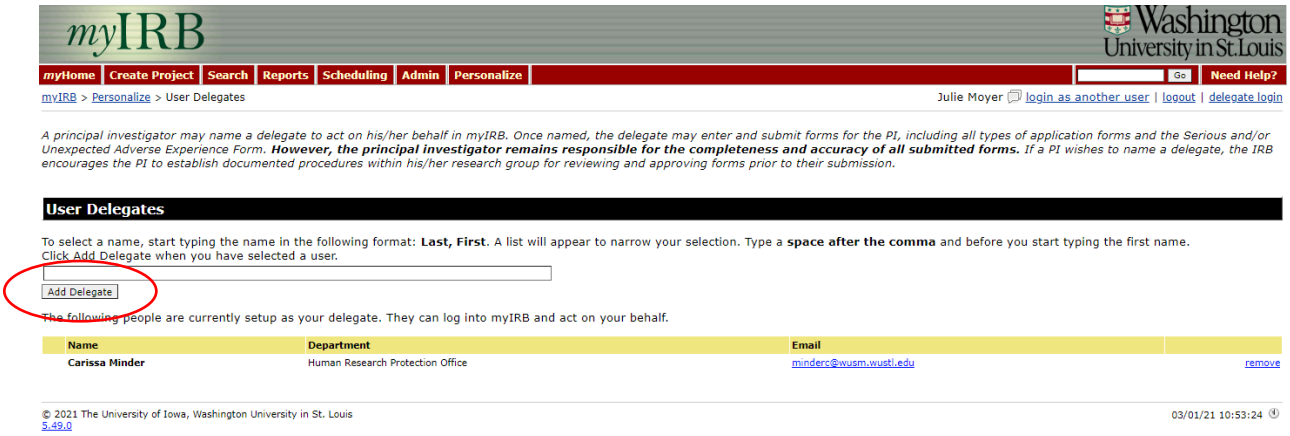
2.3: Delegates to the PI

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

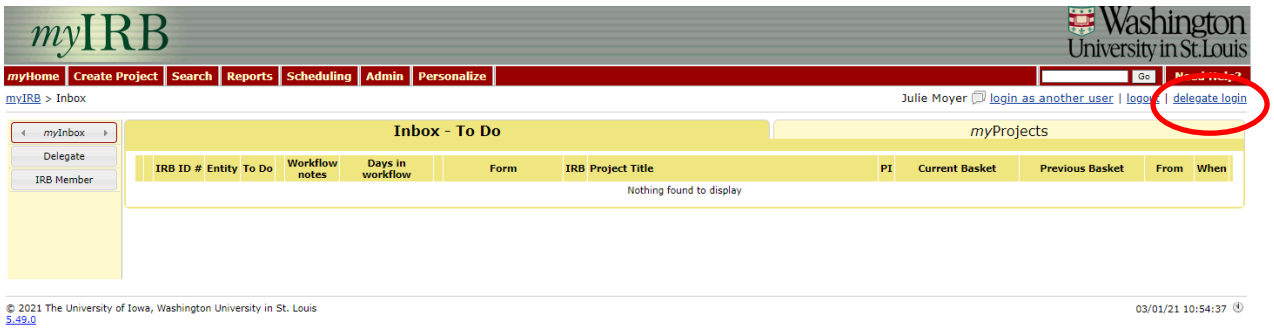
   Those that need to access approved materials such as the consent form should be made delegates.

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

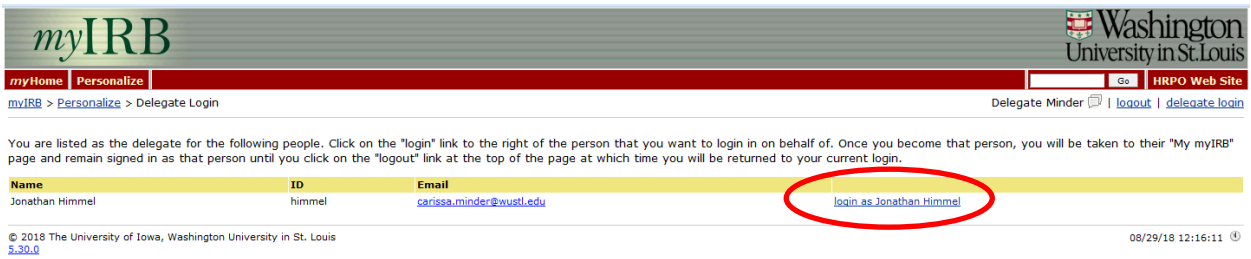
   1) Login using your myIRB HRPO ID and password that you created in Section 2.1.
   2) Click on the **Personalize** on the red menu bar at the top of the page.
   3) Click on the gray button that says **Update my delegates**.
   4) Start typing the last name of the person you would like to act as your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



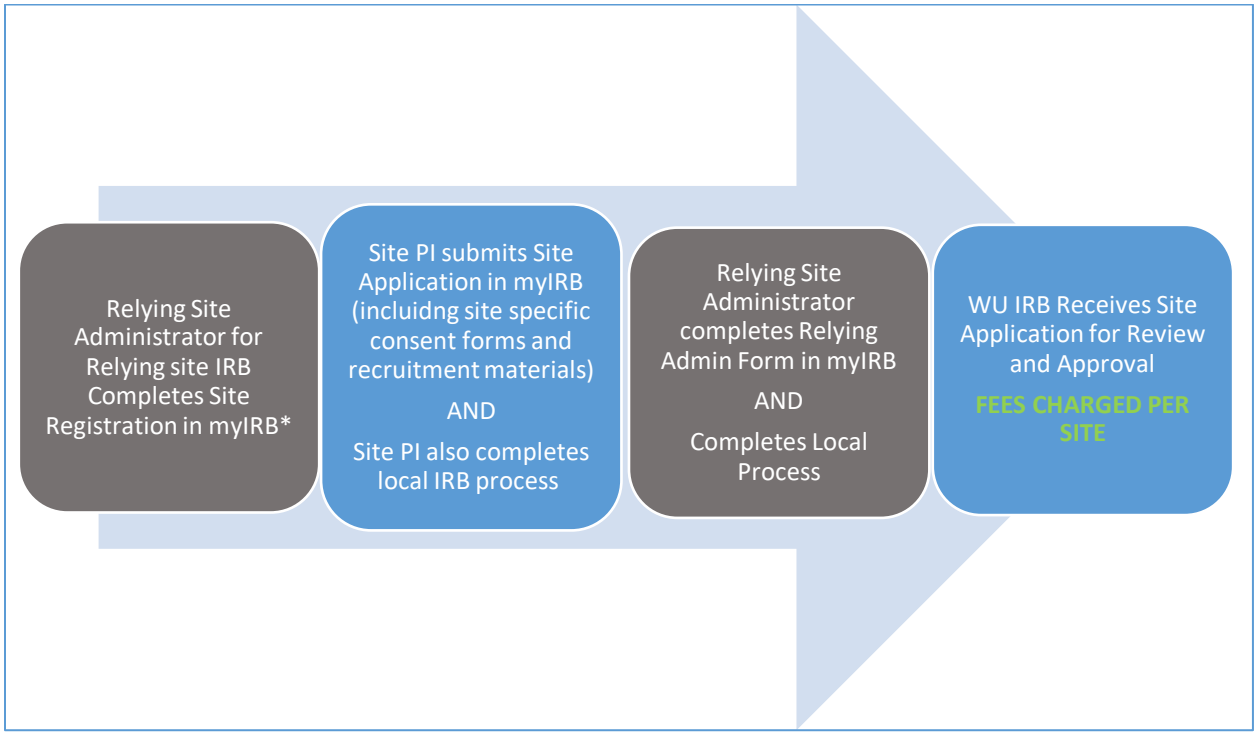
2. If you are a study team member acting as a delegate for a PI to submit an application or address questions you must first log in as the PI.
   1) Click on the **delegate login** link.



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



Section 3: Submitting a Site Application



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

3.1: Site Applications

1. All sites need to submit an **sIRB New Site** application in myIRB to obtain WU sIRB approval to conduct the research at their site. This step will take place after the sIRB New Project is approved by the WU IRB.

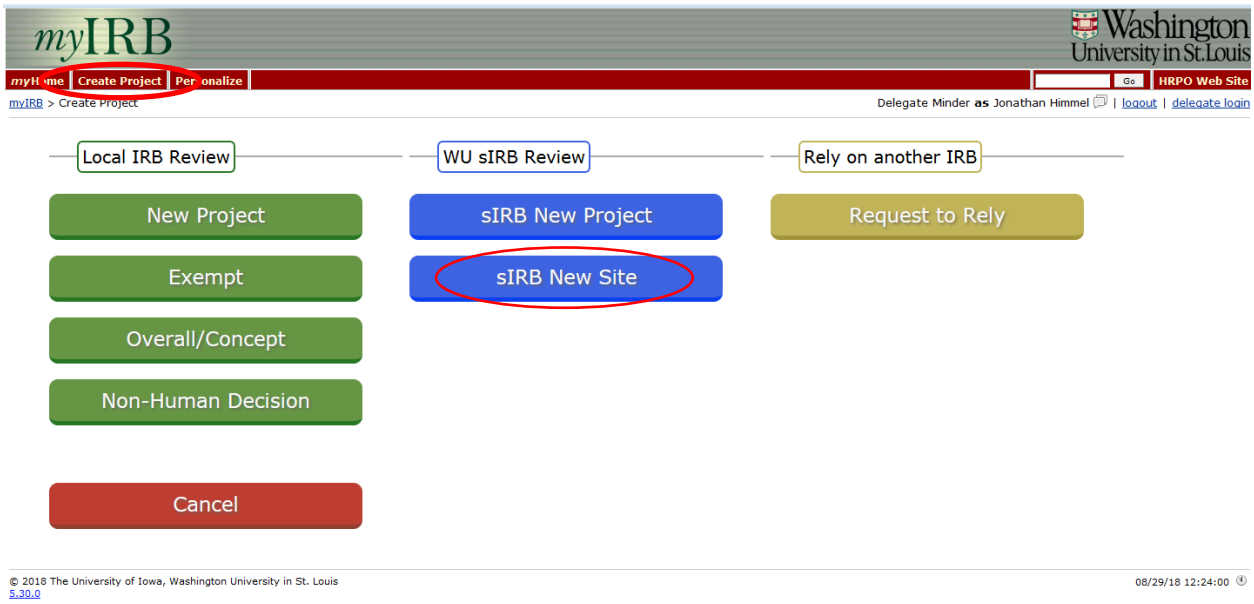
2. Sites will also be required to sign either an addendum to an existing reliance agreement or a new reliance agreement. This process will be handled between the two IRBs and the agreements cannot be signed by site PIs.

3. Local sites should NOT attach a consent form. If a local site requires a consent form, the WU sIRB will use the approved project consent template, 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.)

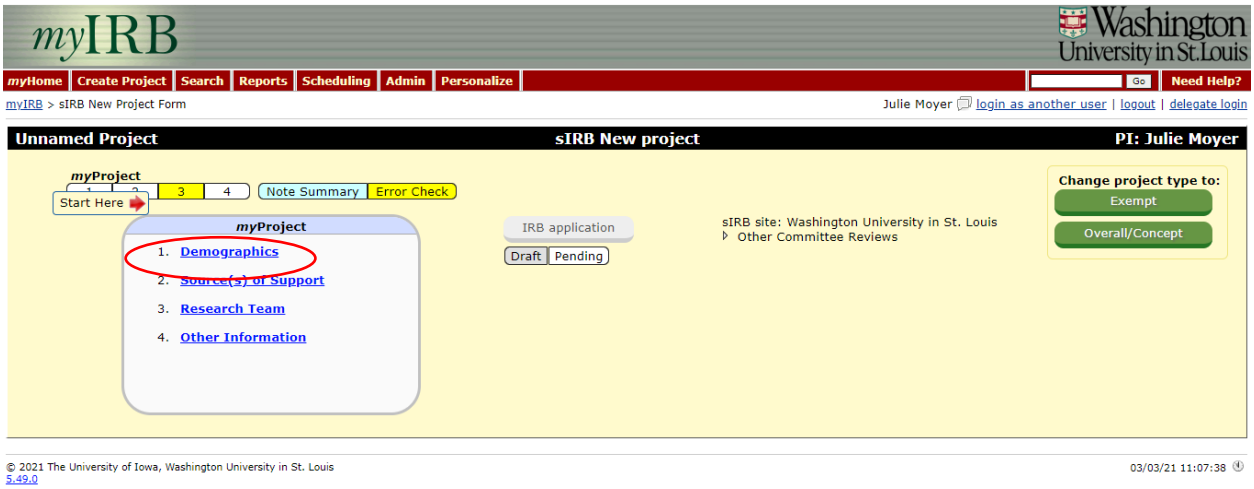
4. Local sites do NOT need to add all research team members in myIRB. Team members are tracked at local sites only. Local processes should be followed to ensure the study team is appropriately trained and qualified. Those that need to access approved materials such as the consent form should be made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

3.2: Submitting the Site Application

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

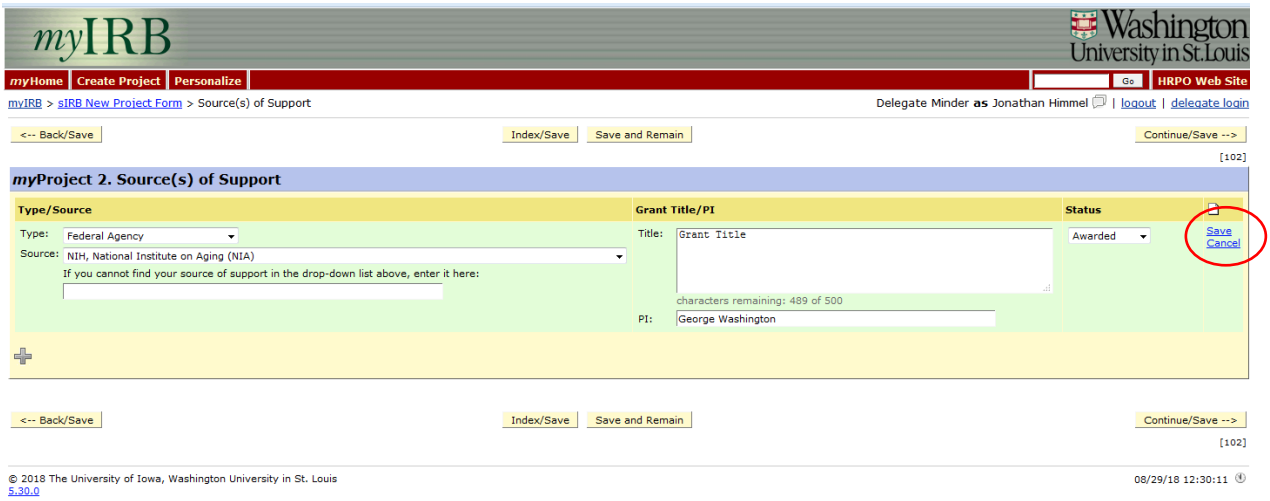


2. You will be prompted to confirm your site PI name and Institution. You will be asked for the IRB ID #.
3. You will then enter the electronic form. To work through the form, start by clicking on the blue **Demographics** link.

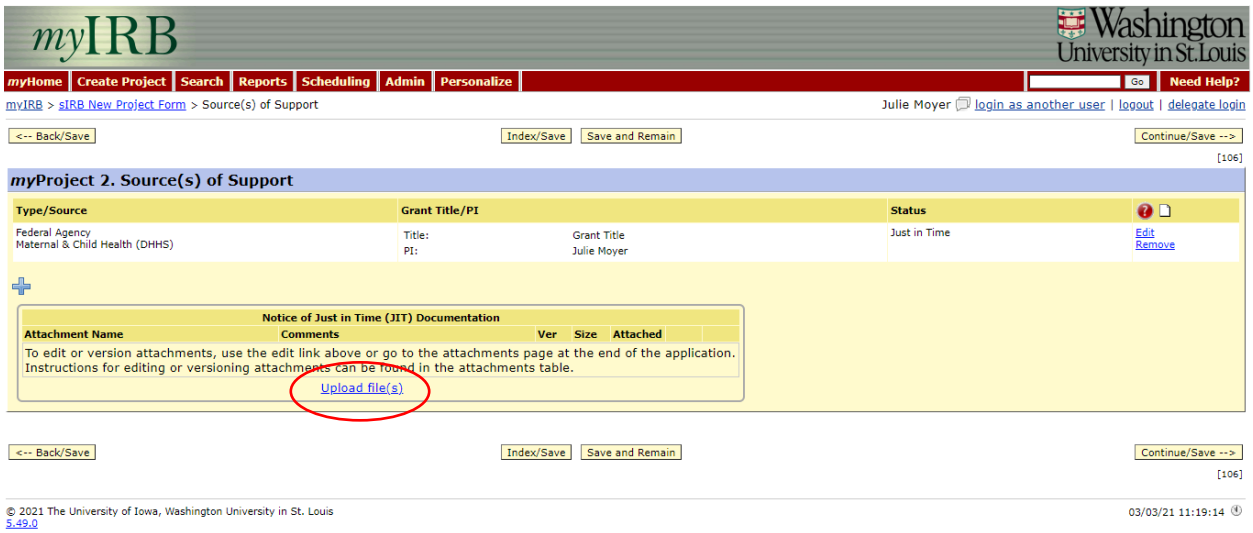


4. You can begin answering questions about the project at your site. The form has smart technology so questions will populate or be suppressed based on the responses to other questions. Use the navigation buttons at the top and bottom of the page to go **Back/Save**, **Index/Save**, **Save and Remain**,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

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

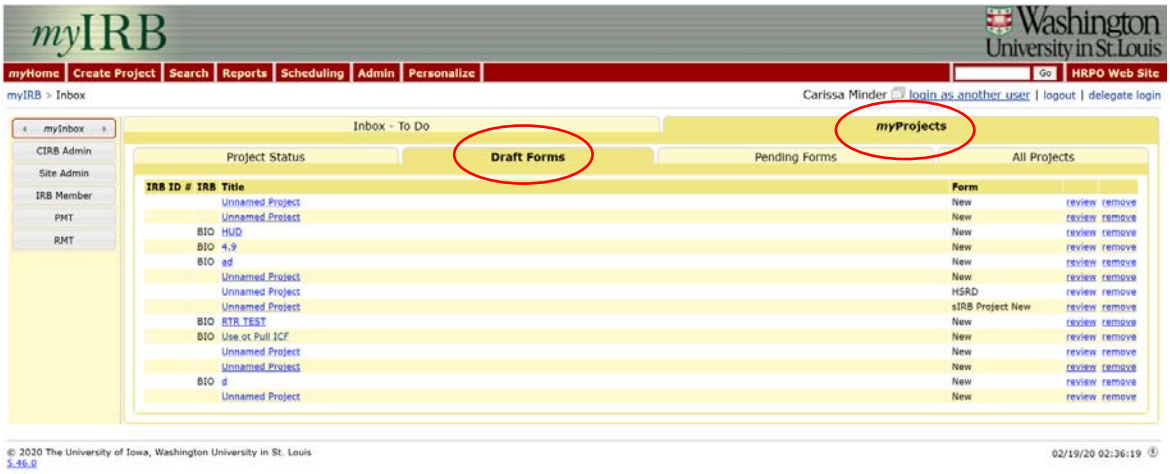


   2) Some questions will prompt a place to upload attachments. Click on the **Upload File** link follow the instructions on the pop up to attach your document(s).



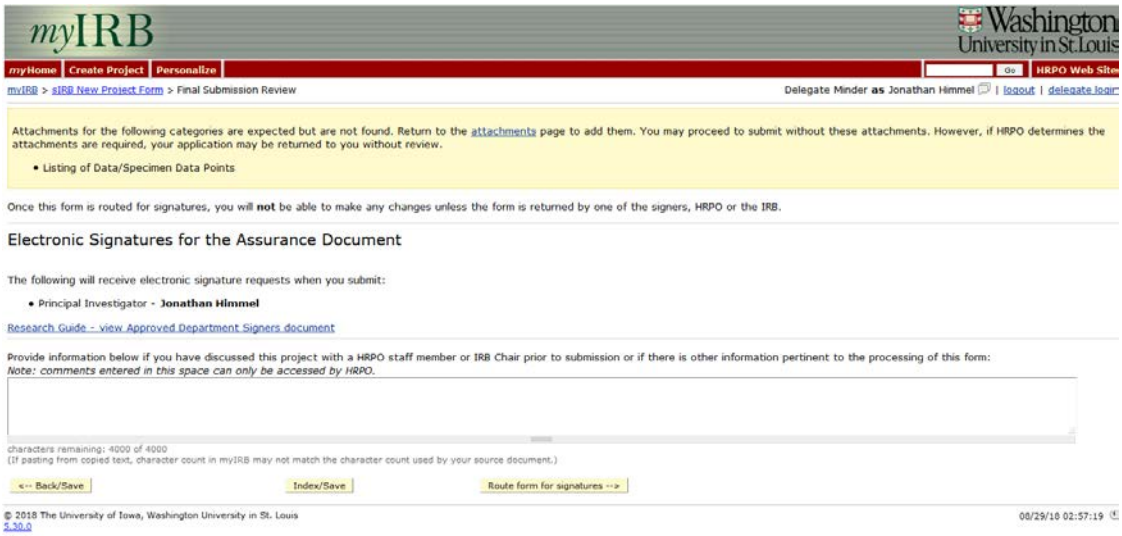
NOTE: Consent files uploaded to myIRB as attachments need to contain a gray IRB stamp box and be in .rtf file format in order to be attached to the application.

5. 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.

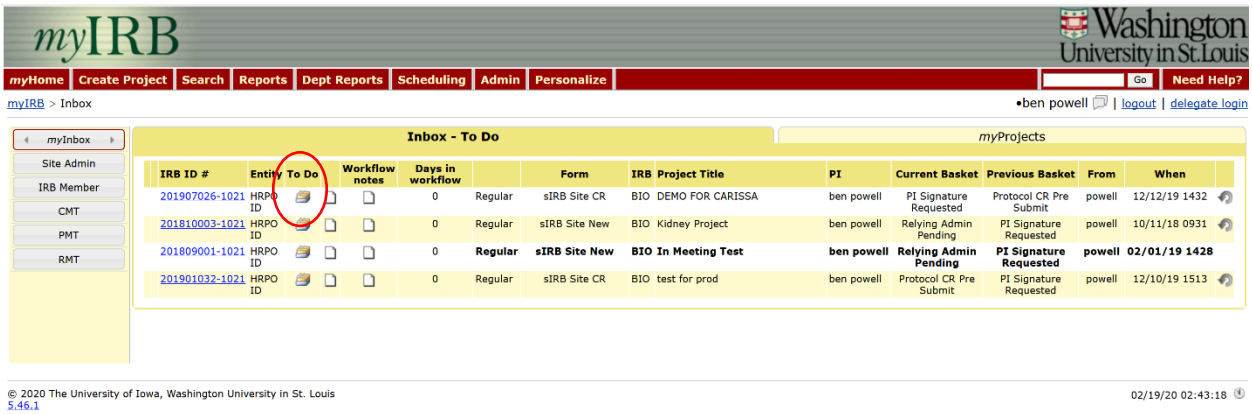


6. When the application is complete, you will be taken to the **Final Submission Review** page. You will be prompted to complete questions and add missing attachments before

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.



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



8. 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

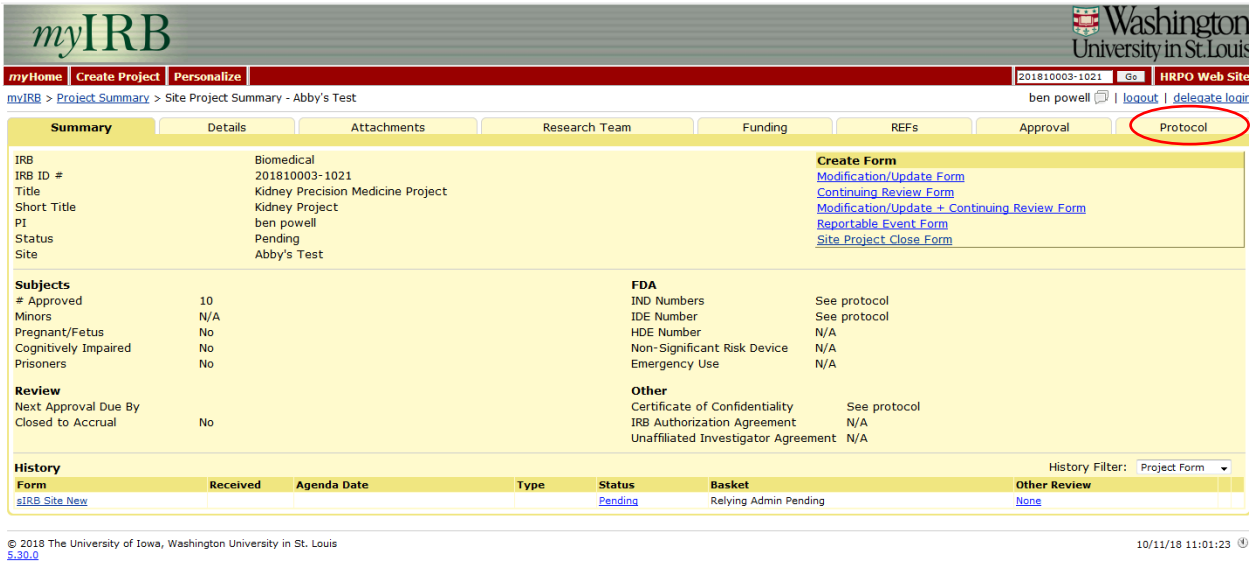
Click on the following link to DENY the signature request:
Deny this signature request

08/31/18 11:02:54

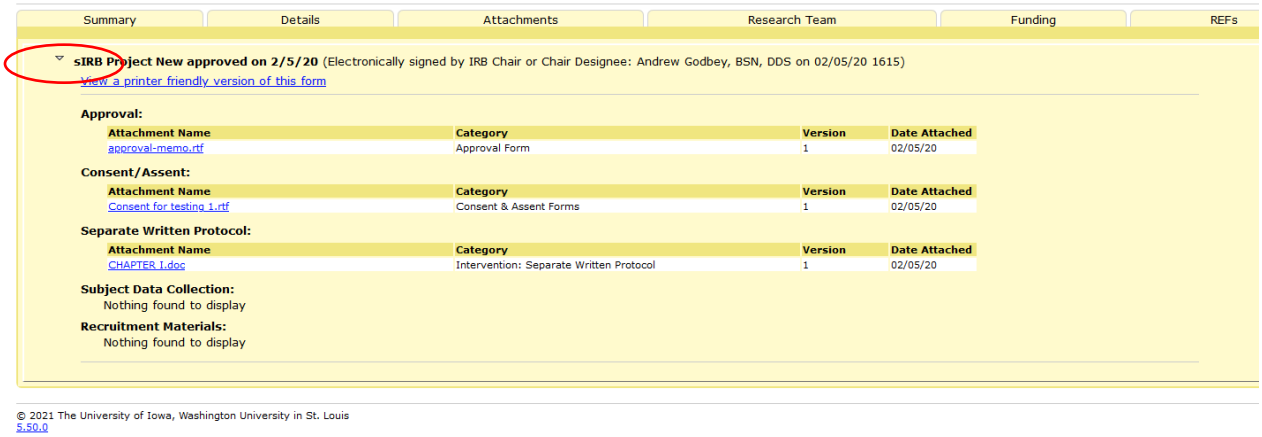
9. At this point, a notice will be sent to your local IRB office administrator letting them know a PI from their institution has submitted a form to the WU sIRB. They will then log in to the system and assess the information and complete the electronic sign off process to defer to the WU sIRB for this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

3.3: Reviewing Approved Protocol Documents

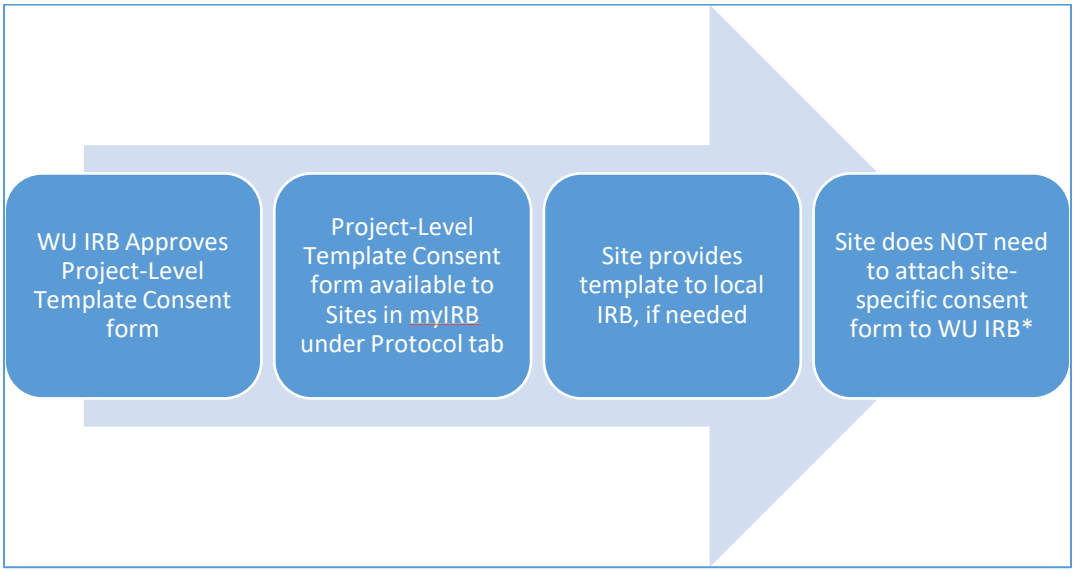
1. If you need to review the approved protocol level materials, go to the **Project Summary** page by entering in the IRB ID # in the search box and hit **Go** or click on the IRB ID # from your Inbox. Once on the Project Summary page, click on the **Protocol** to access documents.



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



3.5: Site Consent Forms



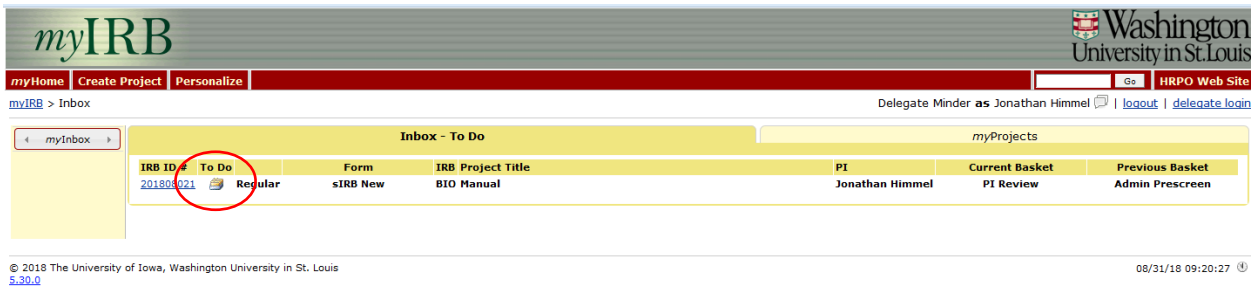
1. *As a part of the review of the overall project, the WU IRB reviews and approves a project-level template consent form that contains marked, limited sections for the inclusion of site-specific information.
2. The project-level template consent form is available in myIRB once the site starts drafting their application. It can be retrieved from myIRB and attached to any local application as required by local policy.
3. Sites do NOT need to provide a site-specific consent form to the WU IRB. The information provided in the Site Registration will be added to the project-level consent template by HRPO staff to create a site-specific consent form for your site. The PI will be notified by myIRB when the site-specific consent form is available for review and editing in the allowed sections.
4. If there are specific areas in the consent form outside of the marked, limited sections that will need to be changed for your site, make these changes to the draft consent form during your review using tracked changes in Word and it will be reviewed by the WU IRB to determine if the changes can be accepted.

3.6: Answering Questions from the WU sIRB

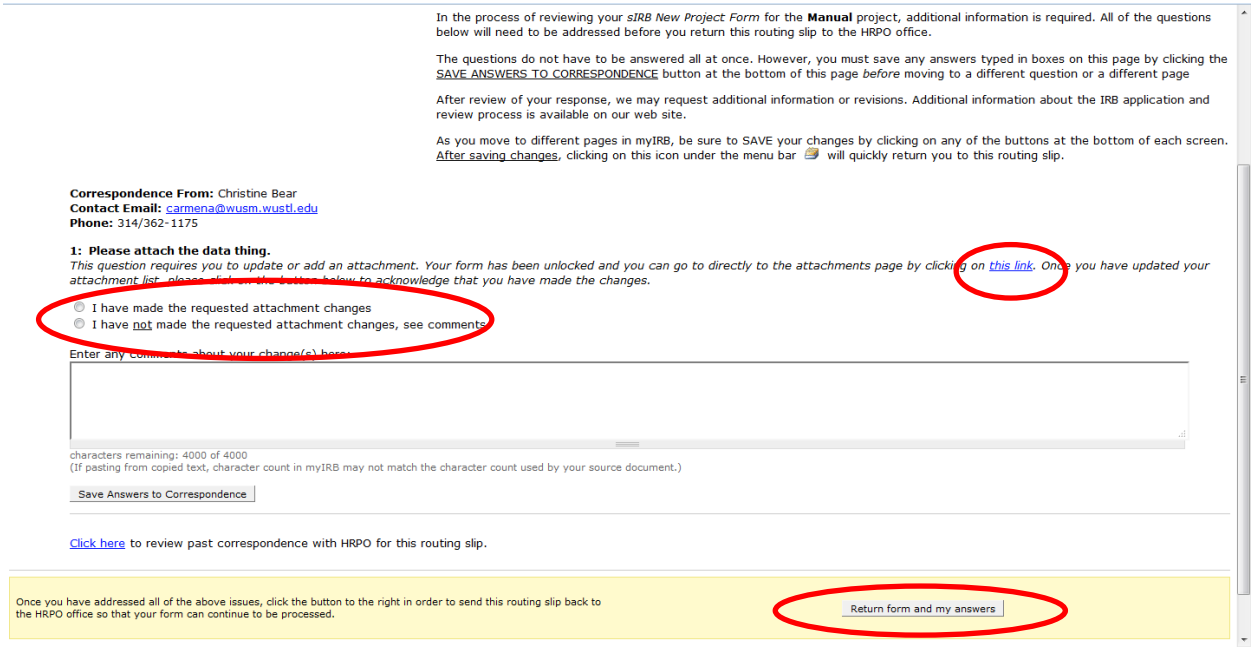
1. If the WU sIRB has questions about your application, you will be contacted through the myIRB system. The PI and their delegates will receive an email from myIRB@wusm.wustl.edu notifying them that there are contingencies to address.

   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.



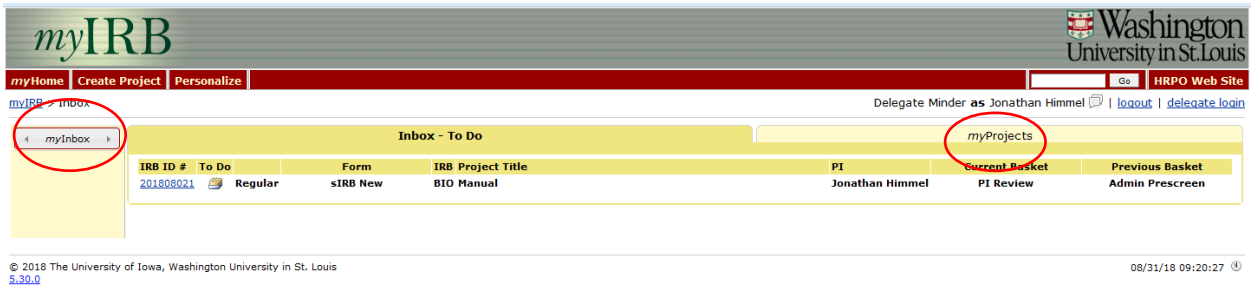
Make the changes to the application and click **Index/Save**. Navigate back to the **Workflow** page with the questions or requested changes using the file folder icon in the upper right hand corner of the page under the red menu bar.

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.

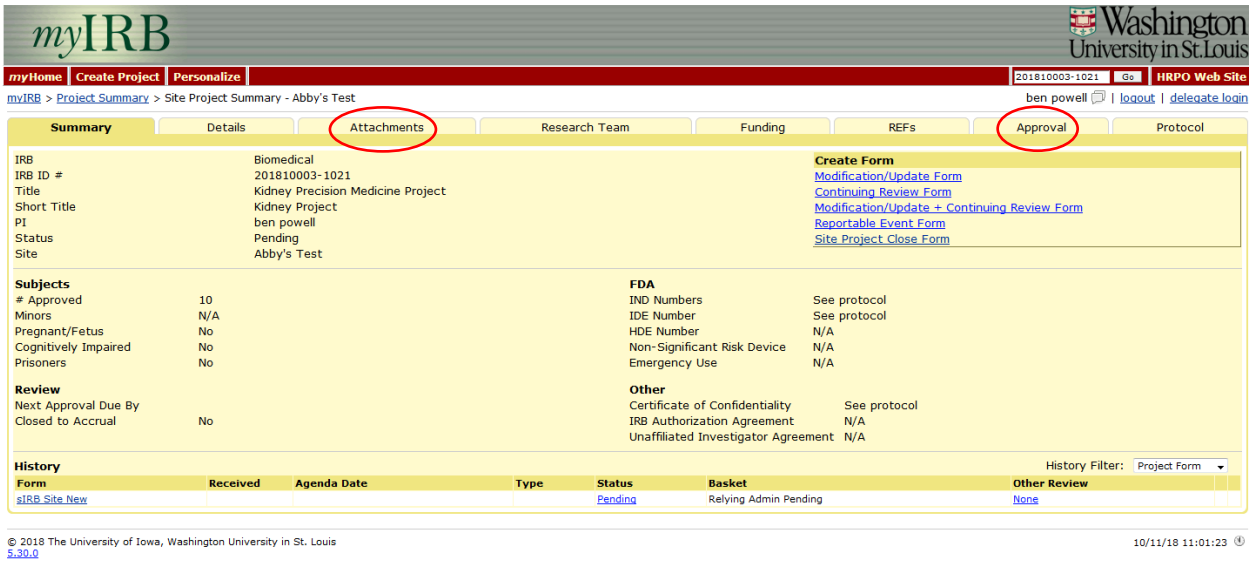
4. The PI and their delegates will receive a notification email from myIRB@wusm.wustl.edu when the project application has been approved by the WU IRB.

3.7: Reviewing Site Approved Materials

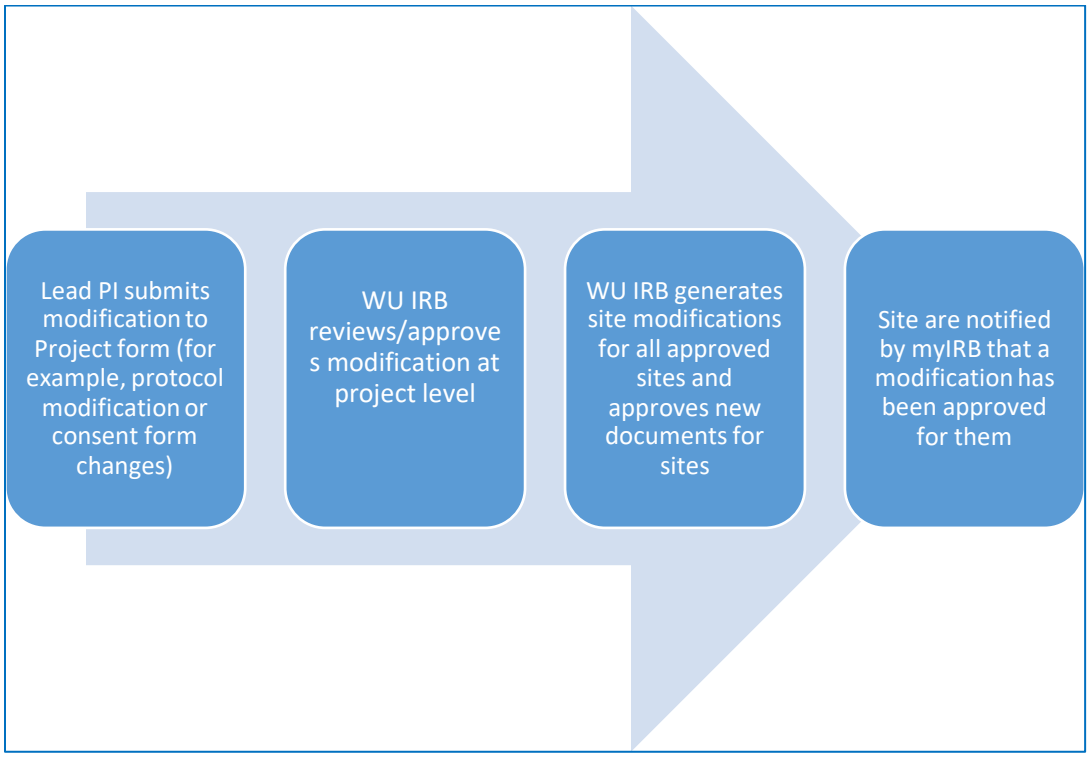
1. To review information submitted by and approved for your site, click on **myProjects** from the ***my*Inbox** page**.** Then click on the **All Projects** tab. You can access study information by clicking the IRB ID #.



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



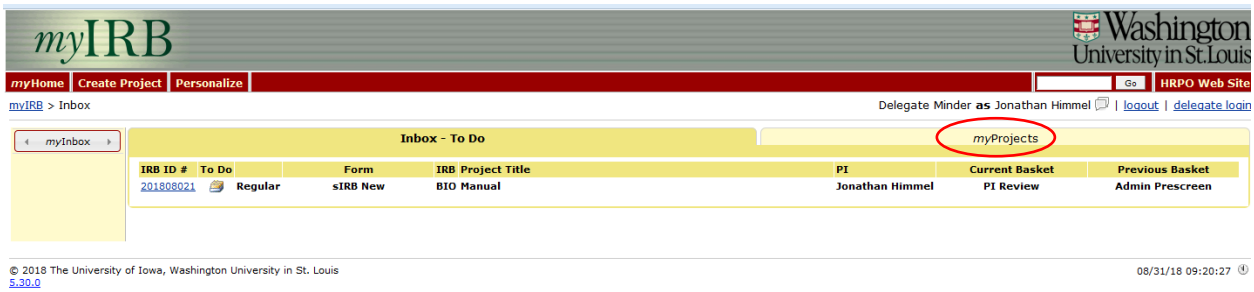
Section 4: sIRB Study Modifications



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

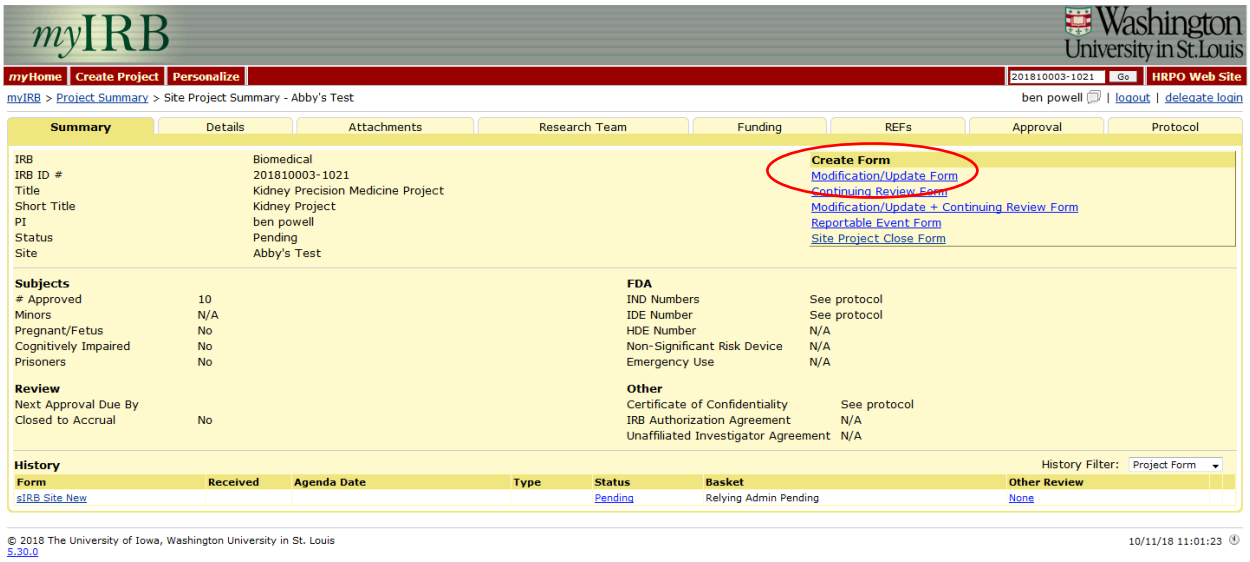
4.1: Submitting a Modification

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

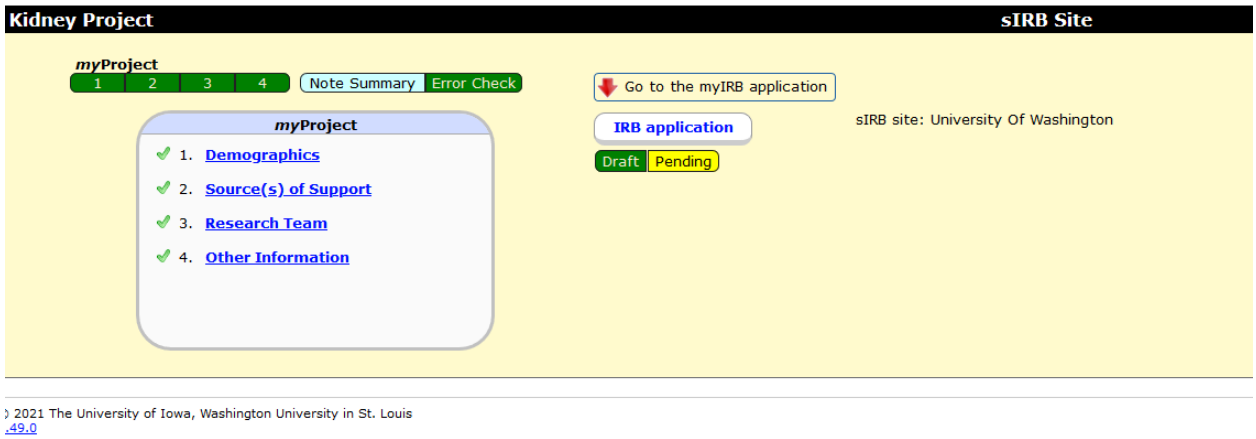


2. Click on the **All Projects** and then click on the blue link with the IRB ID #. This will take you to the **Project Summary** page.

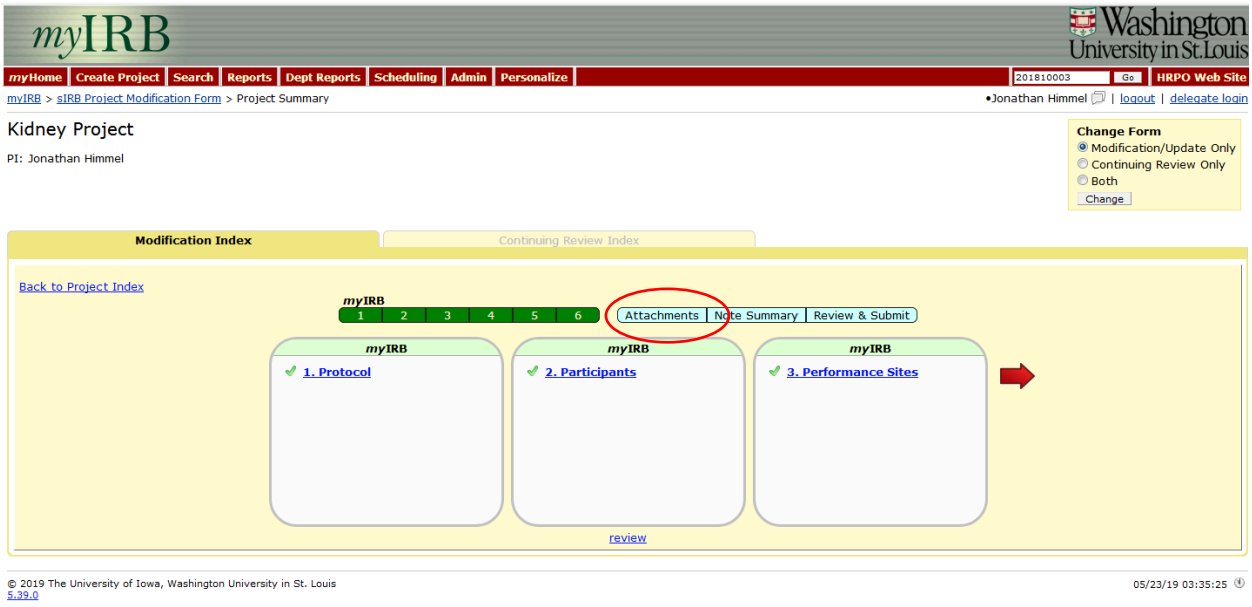
3. Click on **Modification/ Update Form** on the Summary page.



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

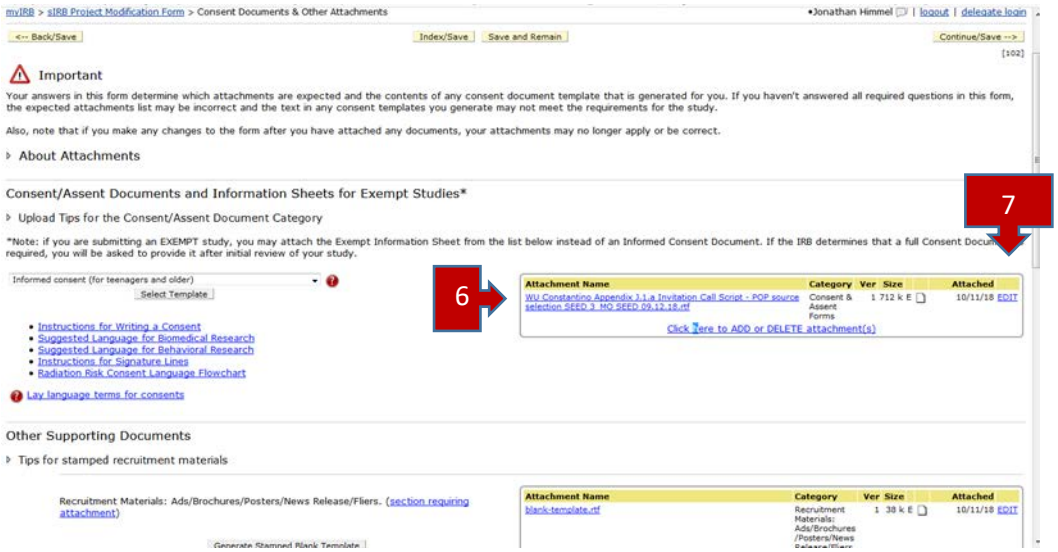


5. To update attachments, navigate to the **Attachments** page by clicking the blue **IRB Application** link the middle of the page shown above and then click the blue **Attachments** button.

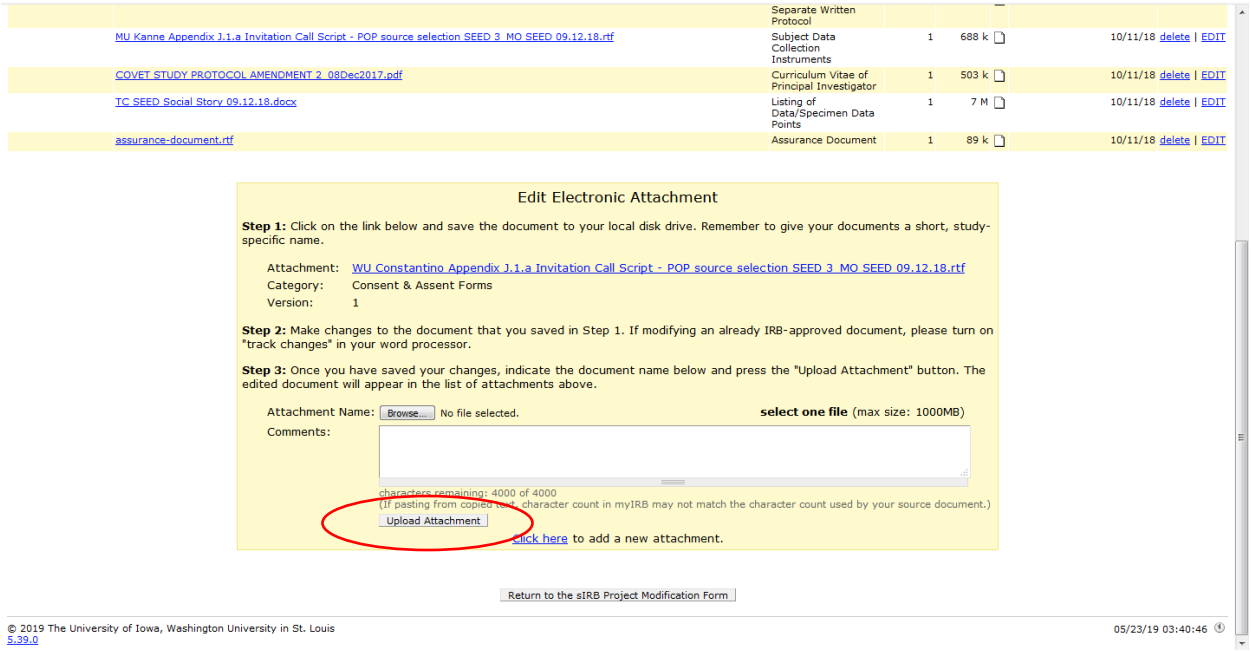


6. When you get to the Attachments page, DO NOT CLICK EDIT! Click on the blue link with the name of the document you want to edit first and save a copy to your computer. Make the appropriate edits using TRACKED CHANGES.

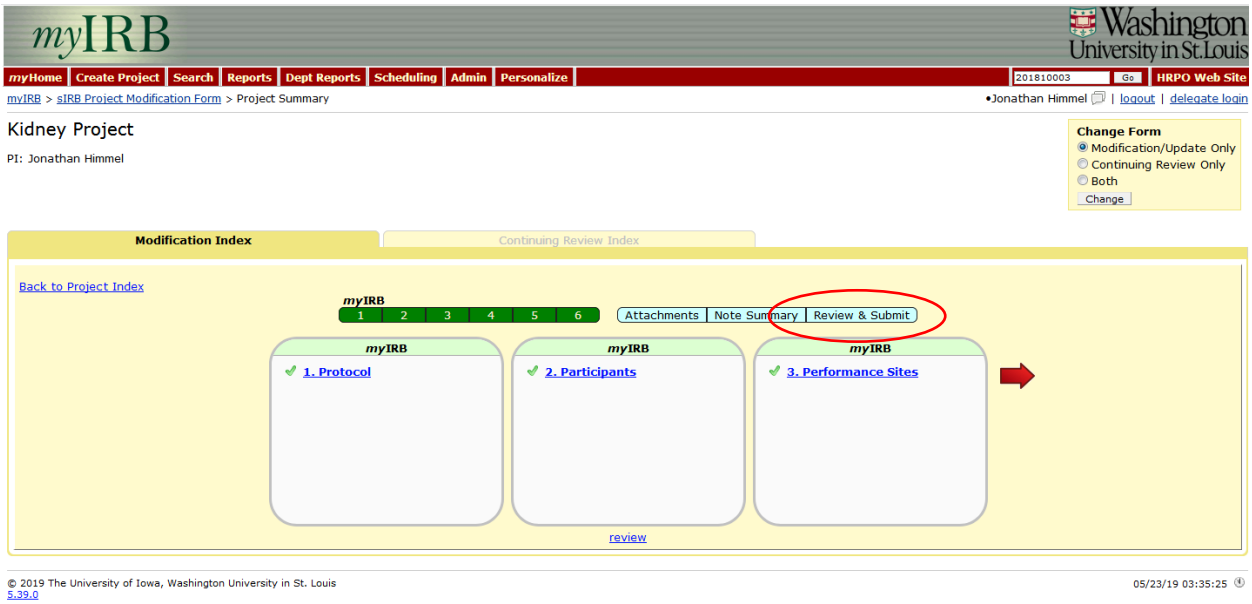
7. Once you have the edited document, click the blue **EDIT** link next to that document.



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



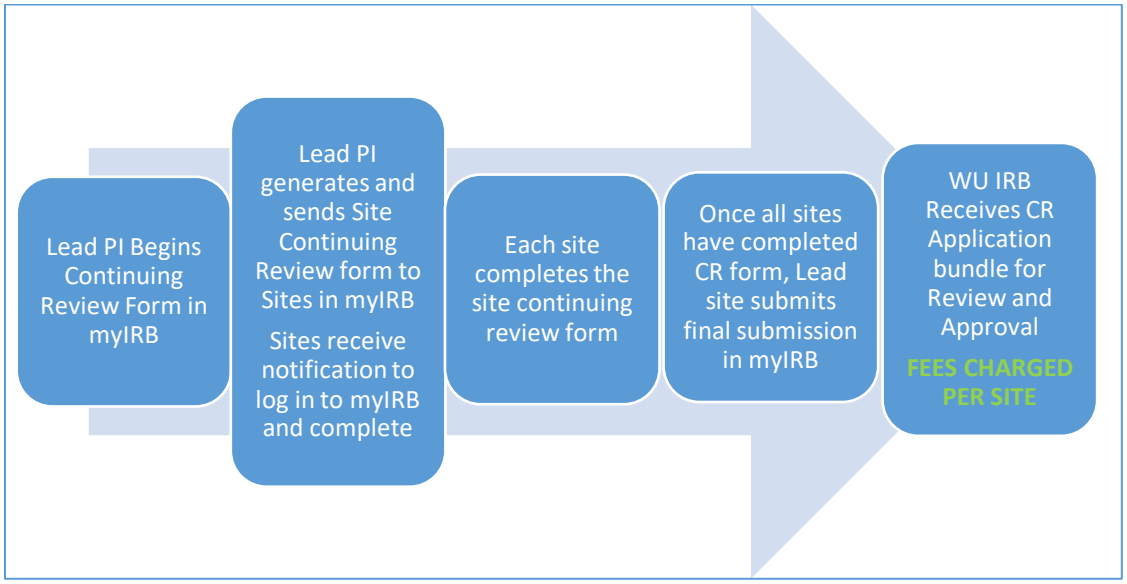
9. Once you have completed your changes, click on the Review and Submit button.



10. 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.

11. 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 5: sIRB Continuing Review Submission

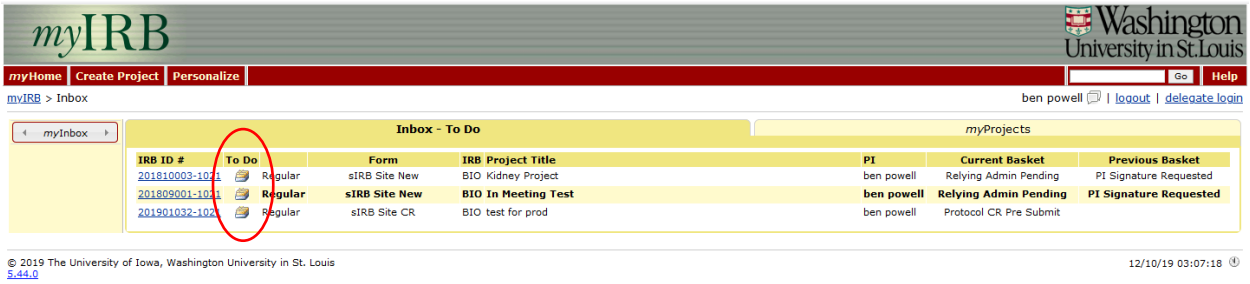


5.1: Submitting a Continuing Review

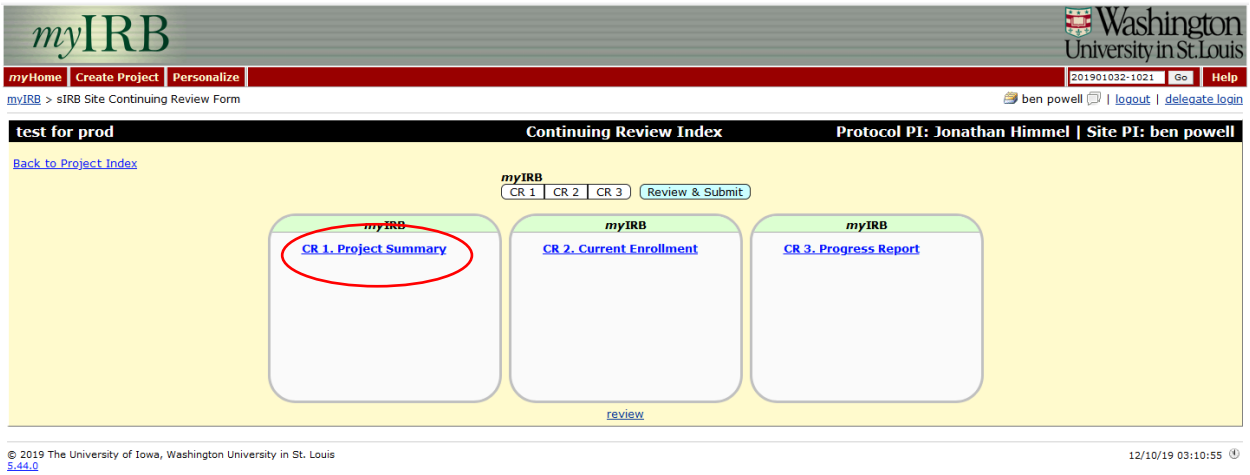
Do NOT start a continuing review form for your site until the Lead PI has started the Project CR.

1. You will receive an email from myIRB telling you that you need to log in and complete your Site Continuing Review form.

2. Go to the PI's Inbox and click on the file folder icon under the **To Do** heading.



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



4. When complete, click the **Route form for signatures** button so the PI can sign the form. If this form is routed for signatures by a delegate, the PI will need to sign in to myIRB, click the file folder icon under **To Do** to access the page where they sign the form. Alternatively, the PI may click on the link in the myIRB email notifying them that their signature is required.

5. Once all sites have completed their information, all the forms will be reviewed together and if the CR is approved, you will receive an email from myIRB letting you know this information.

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

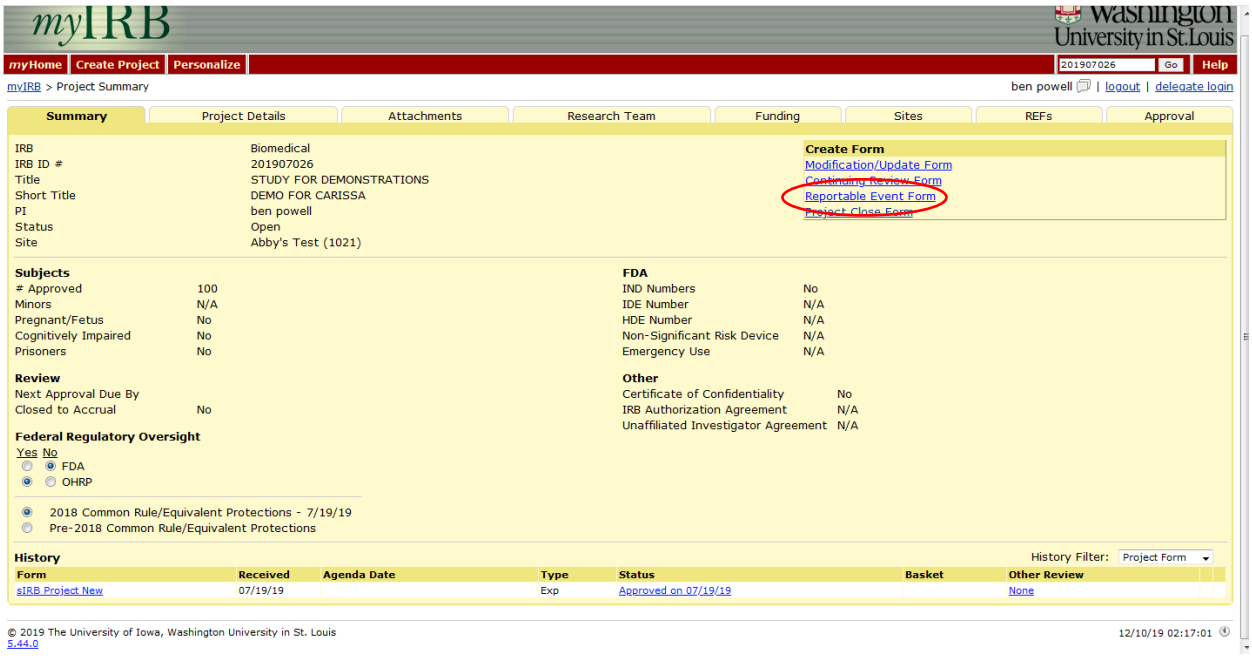
Section 6: sIRB Reportable Events

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

6.1: Submitting a Reportable Event

1. After logging in to myIRB, navigate to the **myProjects** tab and then the **All Projects** tab. Click on the IRB ID # for the study.

2. From the Create Form section, click on **Reportable Event Form**.



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

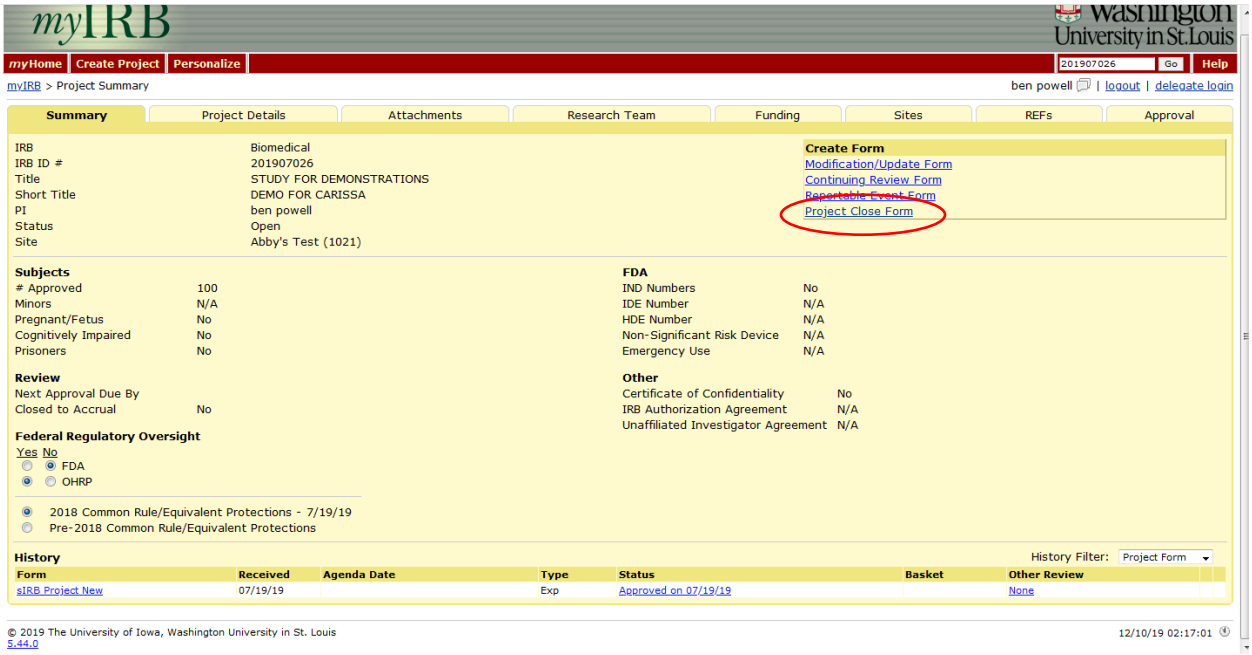
Section 7: sIRB Closure Forms

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

7.1: Submitting a Closure form

1. After logging in to myIRB, navigate to the **myProjects** tab and then the **All Projects** tab. Click on the IRB ID # for the study.

2. From the Create Form section, click on **Site Project Closure Form**.



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

Section 8: Definitions

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

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

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

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

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 9: Frequently Asked Questions

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

See section 2.2, Number 3.

How does the PI "sign" a form?

See section 3.2, Numbers 6-8.

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.