

# *WashU* | **sIRB**

## Single IRB Research Guide

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## **APPLICABILITY**

All research that is funded by NIH and falls under the NIH sIRB Policy (effective January 25, 2018) must use a sIRB for the research conducted in the United States as designated in the funding application.

All research that falls under the DHHS regulations related to Cooperative Research (45 CFR 46.114) (effective January 20, 2020) must use a sIRB for the research that is conducted in the United States. This includes other agencies that have signed onto the Common Rule. A listing of these agencies can be found here:  
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>

A single IRB is not required to be used for:

- research funded by non-federal entities, for-profit entities or unfunded research
- research funded by institutional training grants (T Grants)
- research determined to be Exempt by the IRB
- Foreign sites (If an study involves both domestic and foreign sites, the domestic sites would be expected to use a single IRB and the foreign sites could use their own IRBs or Ethics Boards) Note: WU IRB is NOT able to act as the IRB for foreign sites even if preferred by the PI

NIH FAQs on Single IRB Policy:

<https://grants.nih.gov/faqs#/hs-single-IRB-policy-for-multi-site-research.htm>

# Relying on an External IRB

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## **GENERAL INFORMATION**

The Human Research Protection Office (HRPO) works with investigators who have the role of a *participating* site in a multi-site study to identify and rely upon the appropriate external IRB. To request that HRPO defer IRB oversight to an external IRB, a Request to Rely (RTR) application must be submitted in myIRB.

The process for reviewing the RTR application in myIRB varies based on the external IRB.

- **Option A: Independent IRB**  
Also known as commercial IRBs, these are often used for industry sponsored/ industry initiated trials.
- **Option B: National Cancer Institute (NCI) CIRB**  
This IRB is often used for federally funded cancer research or cooperative group research.
- **Option C: Any other external IRB**  
This could be an IRB at another academic institution, an IRB at a federal agency, such as the NIH, or another other type of IRB.

# Relying on an External IRB

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## **Principal Investigator (PI) Responsibilities when using an External IRB**

BEFORE Study Initiation the PI and study team should:

- Review the [sIRB Decision Matrix](#) to verify when to request to rely on an external IRB.
- Review the [HRPO Fee Schedule](#) to identify any fees associated with submission of an RTR.
  - ✓ If a fee is required, verify that funding is available to pay the identified fees.
  - ✓ Alert the appropriate person in your accounting/finance area that will be paying the fee that an “ID” will be posted in the institutional financial system from HRPO that needs to be paid *within 30 days of submission*.
- Obtain and follow any additional local requirements for ancillary human research protection reviews (RDRC, PRMC, etc.)
  - Please note, if the study you are requesting to defer to another IRB requires review by the Radioactive Drug Research Committee, please wait for the Radioactive Drug Research Committee to contact you with instructions before submitting an application to that committee.
- Submit a RTR to HRPO via myIRB for each protocol
- Ensure research activities are not initiated until:
  - ✓ all institutional requirements for the study including funding and clinical trial agreements are finalized and
  - ✓ the Reviewing IRB has approved the PI’s site for participation in the study.

# Relying on an External IRB

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AFTER Study Initiation the PI and study team should:

- Oversee and conduct the study in compliance with BOTH the Reviewing IRB requirements and the applicable institutional policies and procedures.
- The PI must maintain records of all research and related activities as required by applicable federal, state and local regulations and institutional policies.

## **Modifications/Amendments**

- Protocol Modifications or Amendments, including changes to the consent form that do not change the local context language should not be submitted to the WU IRB
- The PI is required to submit any modifications to the study that affect the local context as a modification to the RTR application in myIRB. These are typically changes to the myProject section of the RTR application including study team and funding changes.
- The PI remains responsible for submitting modifications to the Reviewing IRB either directly or through the sponsor, or their Coordination Center/Lead Study PI. The PI must verify that the Reviewing IRB approves any modifications to the protocol or approved documents prior to their implementation or use unless necessary to eliminate apparent immediate hazards to subjects.

## **Exceptions**

- WU IRB cannot approve protocol exceptions for studies deferred to other IRBs. Requests for Exceptions should be submitted only to the Reviewing IRB.

# Relying on an External IRB

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## Continuing Reviews

- The PI remains responsible for submitting any required information needed for continuing review of the research to the Reviewing IRB or to the Lead PI or sponsor for submission to the Reviewing IRB for approval.
- Continuing review information should not be submitted to the WU IRB
- If at any time study approval lapses, the PI must cease all human subject research work related to the study. If the PI determines that subjects who are already enrolled on the trial may be harmed if research ceases, the PI should follow the Reviewing IRB's procedure for notifying the Reviewing IRB about the individual subject(s) and the justification for remaining on the trial.

## Reportable Events

- Each Reviewing IRB may have different report requirements with regard to what should be reported and the timeframe for reporting.
- The PI is also responsible for notifying their Reviewing IRB of any event meeting the Reviewing IRB's requirement for reporting via the mechanism the Reviewing IRB determines to be appropriate.
- ONLY report the following to the WU IRB as a REF in the myIRB system:
  - ✓ Any unexpected participant deaths
  - ✓ Any unexpected events that are at least possibly related to the research and that may result in permanent or long-term disability

***NCI CIRB ONLY:*** Follow the WU IRB reporting requirements for all reportable events.

# Relying on an External IRB

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## **Platform Trials**

- Platform Trials are typically adaptive multi-arm, multistage trials that allow for evaluation of multiple interventions or populations using interim evaluations and include the addition or removal of interventions or populations (referred to as arms) during the trial. Platform trials have a master protocol and then documentation accompany the platform protocol that provide specific information about each arm of the trial. The reviewing IRB will only review the platform protocol when at least 1 arm is ready to be reviewed and then reviews other arms as modifications to the trial.
- If you are unsure if the trial is this model AND you plan to submit a Request to Rely (RTR) on another IRB, please contact HRPO.
- For the new RTR submissions, please attach the platform protocol and any other documentation about the specific arm or arms that you are ready to begin.
- All ancillary reviews that are required must be completed per policy before the IRB can begin the review of the RTR submission.
- In order for the institution to effectively oversee these trials and meet their obligations, each new arm that will be conducted as Washington University must be submitted as a modification to the RTR.
- When an arm closes, a modification must be submitted to remove that arm and update/ remove the associated information from the RTR form.

# Relying on an External IRB

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## Study Closure

- Once the study is complete and has been closed out with the Reviewing IRB, the PI is responsible for completing a Closure Form in the *myIRB* system.

# Relying on an External IRB

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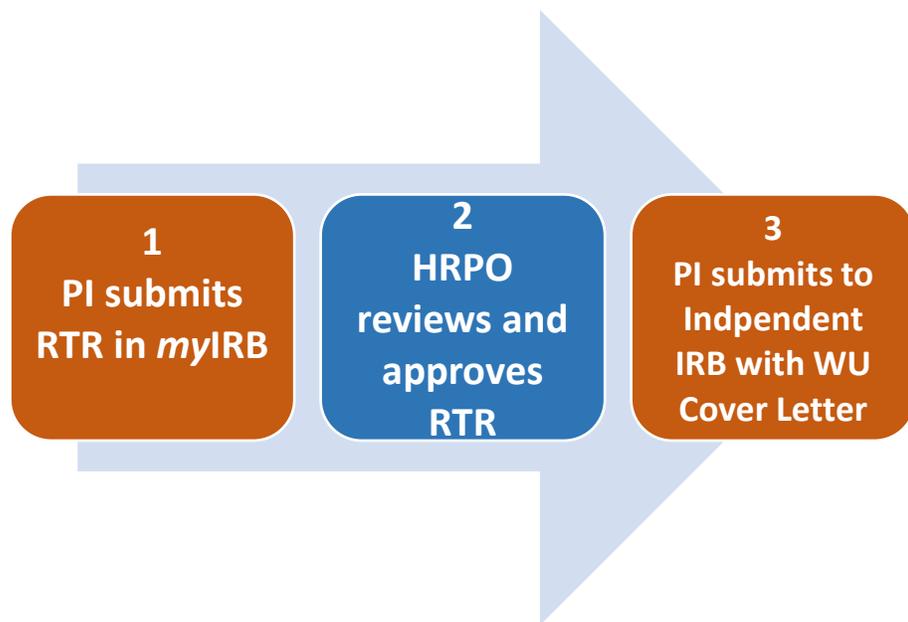
## **RTR SUBMISSION PROCESS**

### **Relying on an Independent IRB**

WU has master reliance agreements with two designated independent IRBs:

- WCG IRB (formerly Western IRB/ WIRB)  
<https://www.wcgirb.com/>
- Advarra (formerly Schulman) <https://www.advarra.com/>

Requests to rely on a different independent IRB will be considered on a case by case basis.



#### *PI Submits RTR Form in myIRB*

1. Review the sIRB Decision Matrix to verify when to request reliance on an independent IRB.

# Relying on an External IRB

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2. Review the HRPO Fee Schedule to identify any fees associated with submission of an RTR.
  - ✓ If a fee is required, verify that funding is available to pay the identified fees.
  - ✓ Alert the appropriate person in your accounting/finance area that will be paying the fee that an “ID” will be posted from HRPO that needs to be paid within 30 days of submission.
3. Go to *myIRB* and complete a Request to Rely application (RTR). Attach the following to the RTR:
  - ✓ Signed Assurance Document (generate document within RTR)
  - ✓ Study Protocol
  - ✓ Signed Injury Language Form (generate from within RTR)
  - ✓ Investigator’s Brochure or Package insert (as applicable)
4. Submit the RTR via *myIRB*.

## *HRPO Review of RTR*

1. HRPO generates and invoice for applicable fees via the WU financial systems.
2. HRPO reviews the RTR and determines if the study meets the criteria to defer IRB oversight to an independent IRB. HRPO staff may ask questions about the RTR via the *myIRB* system during review.
3. If reliance is approved, HRPO will complete the Institutional Submission Cover Page and attach it in *myIRB*. This Cover Page is required by the independent IRB to accept protocols from WU.
4. The RTR is acknowledged by HRPO and the PI may submit to the independent IRB for approval. .

# Relying on an External IRB

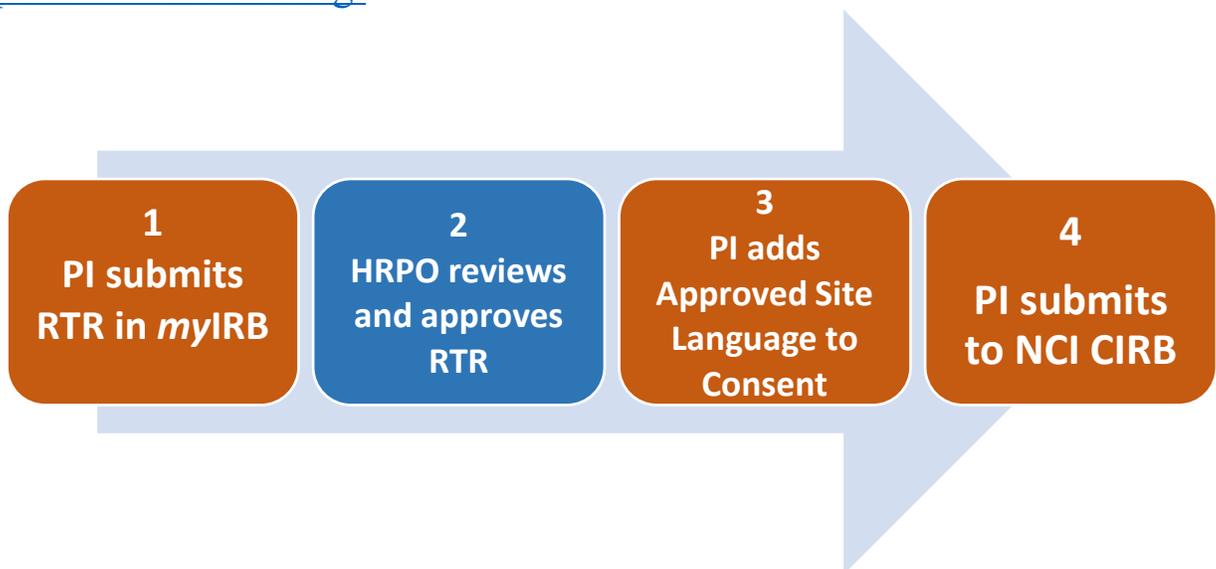
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## 3 *PI Submits to Independent IRB*

1. The PI uses the appropriate electronic submission system to submit to the independent IRB with the Institutional Submission Cover Page.
2. The independent IRB will review and approve the site, providing a site specific consent document using the preapproved site specific language.
3. The PI is responsible for payment of HRPO fees within 30 days of RTR submission regardless of status of study approval.

## **Relying on the NCI CIRB**

WU has been a long-time participant in the NCI CIRB model via a master reliance agreement. Information about the NCI CIRB is available at <https://www.ncicirb.org/>



# Relying on an External IRB

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- 1** *PI Submits RTR Form in myIRB*
1. Go to *myIRB* and complete a Request to Rely application (RTR). Attach the following to the RTR:
    - ✓ Signed Assurance Document (generate document within RTR)
    - ✓ Study Protocol
  2. Submit the RTR via *myIRB*.

- 2** *HRPO Review of RTR*
1. HRPO reviews the RTR and determines if the study meets the criteria to send to the NCI CIRB. HRPO staff may ask questions about the RTR via the *myIRB* system during review.
  2. The RTR is approved by HRPO and the PI may submit to the NCI CIRB for approval.

- 3** *PI Adds Approved Site Specific Language to the NCI CIRB Consent Template*

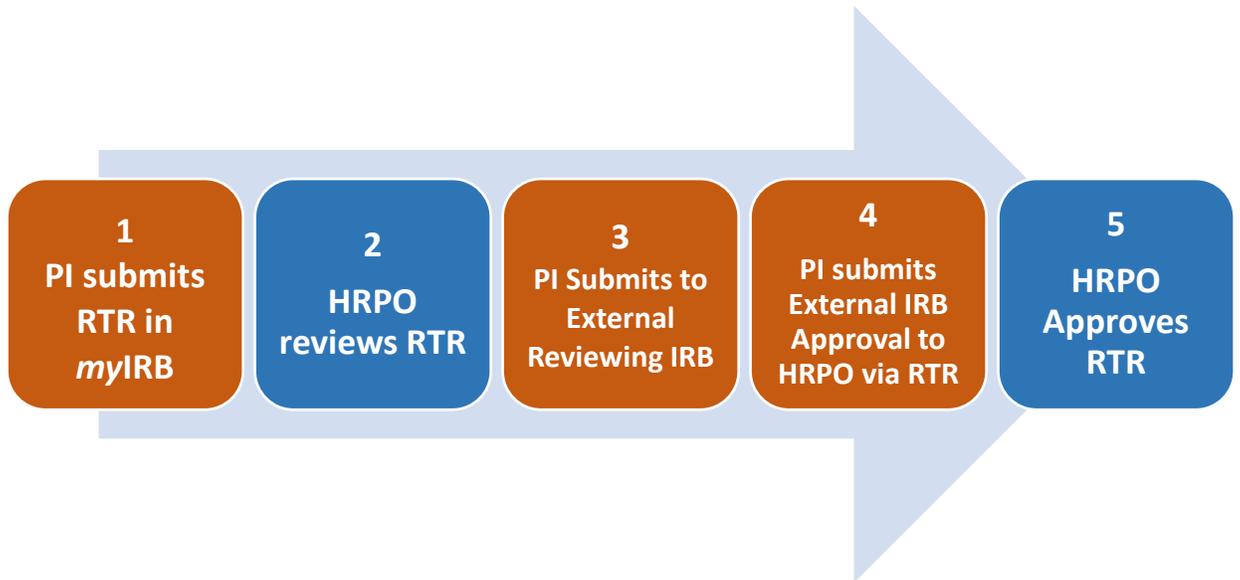
- 4** *PI Submits to NCI CIRB*
1. The PI uses the appropriate electronic submission system to submit to NCI CIRB.
  2. The NCI CIRB will review and approve the site.

# Relying on an External IRB

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## Relying on another External IRB

WU will consider deferring to other IRBs on a case by case basis. Other IRBs could be at academic institutions, not-for-profit entities, at a federal agency, or at other entities.



### ➔ 1 *PI Submits RTR Form in myIRB*

1. Review the sIRB Decision Matrix to verify when to request reliance on an External IRB.
2. Review the HRPO Fee Schedule to identify any fees associated with submission of an RTR.
  - ✓ If a fee is required, verify that funding is available to pay the identified fees.
  - ✓ Alert the appropriate person in your accounting/finance area. HRPO fees need to be paid within 30 days of submission

# Relying on an External IRB

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3. Go to *myIRB* and complete a RTR.

Attach the following to the RTR:

- ✓ Assurance Document (generate document within RTR)
- ✓ Study Protocol
- ✓ Investigator's Brochure or Package insert (as applicable)
- ✓ Documentation of IRB Approval from the IRB reviewing the study.
  - If Reviewing IRB has not yet approved the study, wait to submit the RTR until this is available
  - Documentation must show that the study is currently approved (cannot be expired)
- ✓ Any Forms Received regarding the IRB Reliance, for example:
  - IRB Authorization Agreements
  - Local context forms
  - Site specific applications to rely or determinations forms
  - Template consents
  - Any other documents received from the Reviewing IRB or Coordinating Center related to reliance or IRB review

4. Submit the RTR via *myIRB*.

# Relying on an External IRB

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## 2 → HRPO Review of RTR

1. HRPO reviews the RTR and determines if the study meets the criteria to send to the Reviewing IRB. HRPO staff may ask questions about the RTR via the *myIRB* system during review.
2. HRPO will manage the completion of any reliance agreements or forms that the Reviewing IRB or Coordinating Center require be completed related to IRB reliance. Agreements between entities for IRB reliance are NOT included in contracts or subawards.
  - a. If the determination is made that WU will rely on the designated external IRB and a new reliance agreement is required, the agreement will be reviewed by HRPO and the Office of General Counsel.
  - b. HRPO will communicate any requested changes to the agreement directly to the reviewing entity and obtain the required signature on the agreement.
  - c. HRPO will keep the local PI apprised regarding the status of the agreement.
3. HRPO will notify the PI via *myIRB* when a determination is made to rely on the external sIRB.
  - a. HRPO will insert the required site specific language into any informed consent documents (as applicable.) The final version of the informed consent document will be attached to the RTR in the *myIRB* system. Alternatively, HRPO will work directly with the Reviewing IRB to provide required consent language via the mechanism required by the Reviewing IRB.
  - b. HRPO will return the RTR to the PI in a *pending state to HOLD* until final approval is received from the Reviewing IRB.

# Relying on an External IRB

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## *PI Submits to External Reviewing IRB*

1. The PI will work with the Reviewing IRB or Coordinating Center to determine how to submit their IRB application to the designated Reviewing IRB. This may be via an electronic process or paper depending on the Reviewing IRB's requirements.
2. The Reviewing IRB will review and approve the PI's site and provide any site specific approved documents such as informed consent documents, recruitment materials etc.

## *PI Provides Reviewing IRB Approval to HRPO*

1. PI attaches Reviewing IRB's approval letter and approved consent form (if applicable) to the RTR.
2. PI routes the RTR back to HRPO via the myIRB system.

## *HRPO provides final approval of the RTR*

# WU as Reviewing IRB/ Single IRB (sIRB)

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## **REQUESTING WU BE THE IRB AND sIRB BUDGETING**

Washington University IRB does act as a single IRB. However, a decision about acting as the single IRB will be made on a case-by-case basis depending on the costs of sIRB review, number, type, and location of sites, complexity of the protocol, current capacity of the WU IRB, and ability to meet study review time lines. The WU IRB will be considered as having right of first refusal for the role of sIRB for all studies where WU is the prime awardee for the grant. Please see the Washington University Policy for use of a single IRB (sIRB) in multi-site research studies. [sIRB Policy](#)

PIs cannot agree that the WU IRB will act as the sIRB until they have completed the sIRB Intake Form and received confirmation that WU IRB will act as the IRB and a budget for the cost of the sIRB services. Complete the form linked here to request that WU serve as the single IRB: [sIRB Intake Form](#)

If the study is grant funded, this form should be completed PRIOR to grant submission.

HRPO will review the request and ensure WU IRB is the appropriate IRB to act as the sIRB and provide a budget that can be used for the grant submission.

Fees apply when the WU IRB serves as the single IRB for a multi-site study. Each site will be charged with the exception of the WU site. Fees will vary depending on the number of sites and length of study. Fees apply regardless of funding. [HRPO Fee Schedule](#)

## **WU as Reviewing IRB/Single IRB (sIRB)**

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When WU IRB acts as the sIRB, HRPO will provide information and instructions on the submission process to the lead PI and site PIs. The process is also highlighted in this document.

# WU as Reviewing IRB/Single IRB (sIRB)

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## **EXEMPT RESEARCH**

Single IRB policy and regulations do not apply to exempt research. However, on a case by case basis, the WU IRB will consider making exempt determinations for other institutions if they do not have their own IRB to make the exempt determination and other limited reasons.

Contact HRPO to determine if your Exempt Research would be considered for single IRB review.

## **STUDY MANAGEMENT**

The PI and study team should plan to have resources and time available to assist and follow up with sites during the course of the study to manage the single IRB. Sites often need reminders and assistance from the lead study team when a single IRB is used. HRPO is happy to answer specific questions and talk with study teams about issues but is not able to proactively follow up with individual sites to ensure sites are moving forward with the process.

# WU as Reviewing IRB/Single IRB (sIRB)

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## **RELIANCE AGREEMENTS**

A Reliance Agreement is a written agreement between entities participating in multi-site research that establishes who will be the IRB of record for the 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.

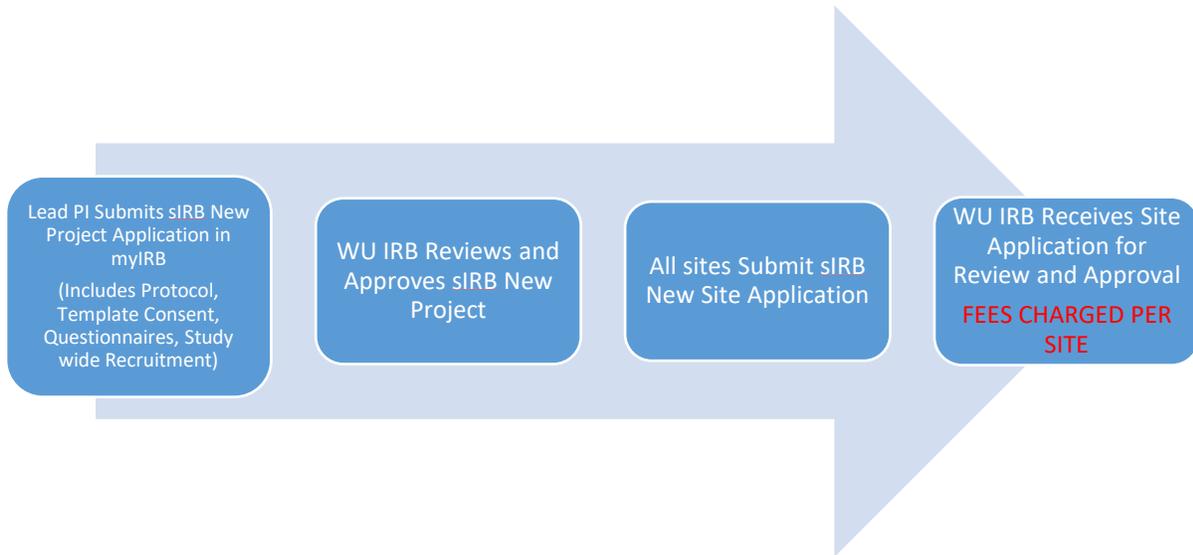
When WU is the designated IRB of record, the WU HRPO is responsible for ensuring that a reliance agreement is in place and that appropriate documentation is maintained. The reliance agreement will be approved and executed by the appropriate officials of the organizations involved.

In most circumstances, the WU prefers to use the SMART IRB Master Reliance Agreement. If relying sites have not signed the SMART IRB agreement, an alternative reliance agreement can be provided by WU. <https://smartirb.org/>

WU HRPO will provide the appropriate reliance agreement or documentation to each site when instructions are sent regarding submission to the WU IRB. These documents should be provided to the site's IRB or appropriate institutional research official and should not be completed by the site PI or study team.

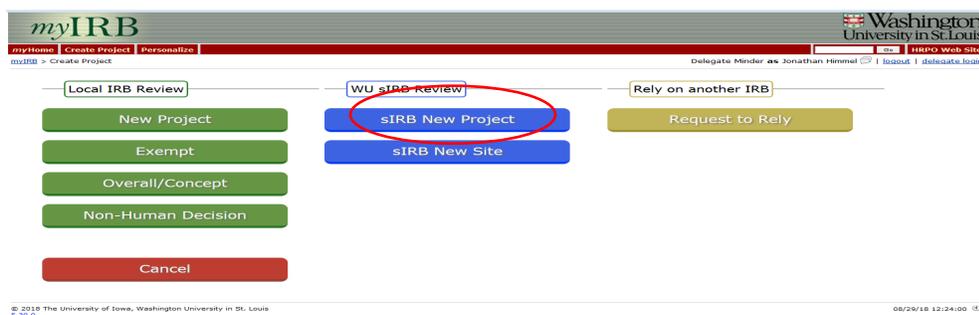
# WU as Reviewing IRB/Single IRB (sIRB)

## HOW TO SUBMIT A SINGLE IRB STUDY IN MYIRB



## sIRB New Project

1. After logging in to myIRB, select sIRB New Project. You will be prompted to confirm your PI name and Institution.



## WU as Reviewing IRB/Single IRB (sIRB)

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2. You will complete the sIRB New Project application and this describes the overall study. It will be used for the IRB to review the overall protocol and study plan. This application's approval is NOT approval for the WU site to conduct the study. The WU site, in addition to all the other sites, will need to submit a sIRB New Site application which is described later.
3. If a consent form is required for this study, you will be required to create a study consent for approval by the WU IRB. This consent form will be approved with certain sections that will be allowed to be edited by the other sites. Write a consent form using the WU IRB template as you usually would. HRPO will then use this document to create the template consent form with the appropriate sections marked.
4. This submission should also have the protocol, any questionnaires to be used by all sites, and any study-wide recruitment documents such as the study website.
5. sIRB applications in myIRB have an electronic signature assurance process. When you are ready to submit the study you will be prompted to sign the assurance (if you are the PI) and route the form for signatures. Once the PI has signed the form, it will be sent to the Department Chair for signature. Once that is completed, the study will be sent to the IRB for review.
6. Once the sIRB New Project is approved, all the sites- including the WU site- will need to submit an sIRB New Site application to obtain approval to conduct the research at the site.

# WU as Reviewing IRB/Single IRB (sIRB)

## sIRB Site Application

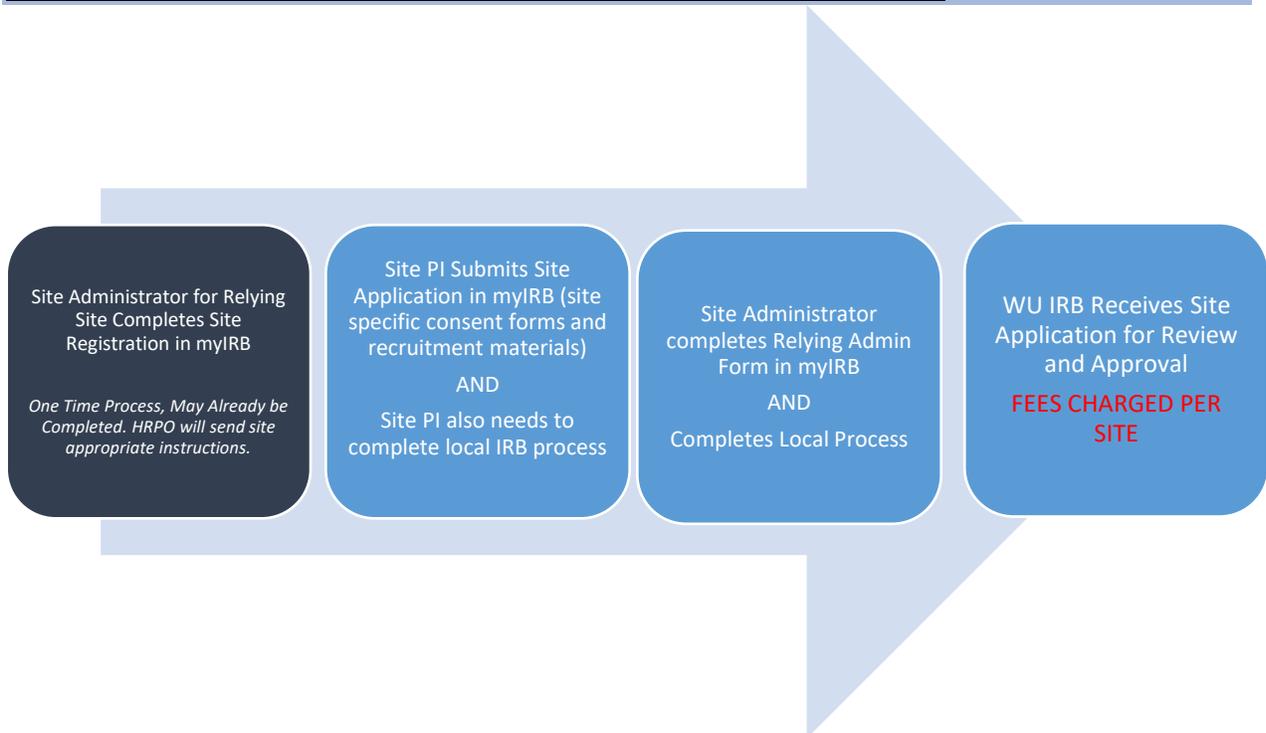
1. Select sIRB New Site. You will be prompted to confirm your PI name and Institution. You will be asked for the IRB ID Number.



2. If a consent form is required for this study, you do not need to attach one at the time of submission. You will be provided an editable template to complete during the review process.
3. Do NOT attach any questionnaires or study-wide recruitment documents that have already been approved.
4. Attach any WU specific recruitment materials.
5. sIRB applications in myIRB have an electronic assurance process. When you are ready to submit the study you will be prompted to sign the assurance (if you are the PI) and route the form for signatures. Once the PI has signed the form, it will be sent to the Department Chair for signature. Once that is completed, the study will be sent to the IRB for review.

# WU as Reviewing IRB/Single IRB (sIRB)

## SITE SUBMISSIONS AND SITE MANAGEMENT



### sIRB New Site Application

1. All the sites 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, HRPO will request that the study team provide them a list of sites and site contact information. HRPO will emails the site PI, study team contacts and IRB with specific instructions for their site on how to submit a sIRB New Site application.

Sites will NOT be asked to attach a consent form. If a site requires a consent form, the WU sIRB will use the approved template and insert site specific required language in to the consent. This language is provided by the site's IRB using a Site Registration process.

# WU as Reviewing IRB/Single IRB (sIRB)

## 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 # link to view site specific information. You can use this information to follow up with sites who have not completed their applications.

The screenshot shows the myIRB interface for a project. The 'Sites' tab is highlighted with a red circle. The project details are as follows:

Summary		Project Details	Attachments	Research Team	Funding	Sites	REFs	Approval
IRB		Biomedical						
IRB ID #		201810003						
Title		Kidney Precision Medicine Project						
Short Title		Kidney Project						
PI		Jonathan Himmel						
Status		Open						
Site		University Of Washington						

**Subjects**

		FDA	
# Approved	1500	IND Numbers	No
Minors	N/A	IDE Number	N/A
Pregnant/Fetus	No	HDE Number	N/A
Cognitively Impaired	No	Non-Significant Risk Device	N/A
Prisoners	No	Emergency Use	N/A

**Review**

		Other	
Next Approval Due By	10/10/19	Certificate of Confidentiality	Received
Closed to Accrual	No	IRB Authorization Agreement	N/A
		Unaffiliated Investigator Agreement	N/A

**History**

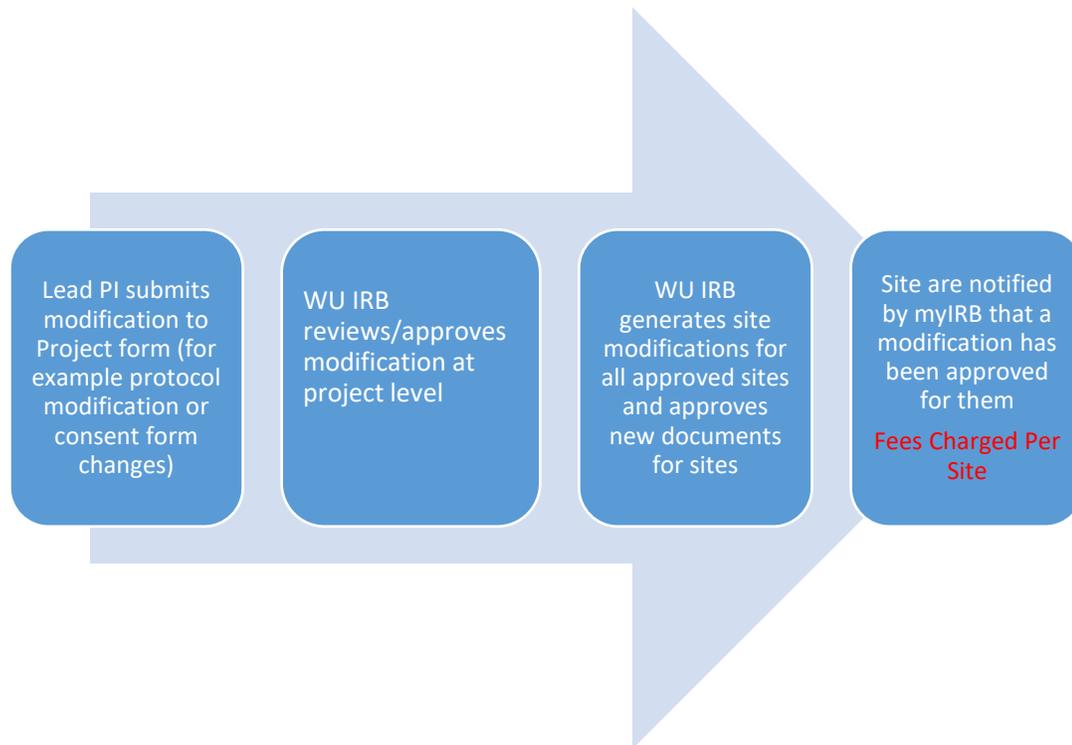
Form	Received	Agenda Date	Type	Status	Basket	Other Review
<a href="#">sIRB New</a>	10/11/18		Exp	<a href="#">Approved on 10/11/18</a>		<a href="#">None</a>

© 2018 The University of Iowa, Washington University in St. Louis  
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# WU as Reviewing IRB/Single IRB (sIRB)

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## sIRB STUDY MODIFICATIONS

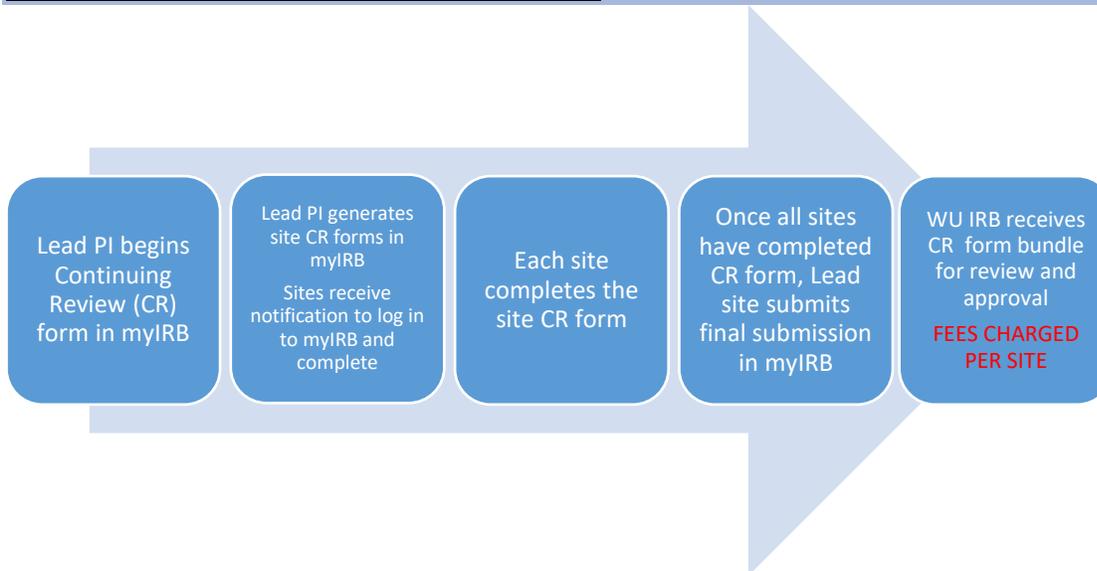


1. Changes that need to be made to the protocol or other study-wide information should be submitted as a modifications to the project application.
2. Once the modification of the project application is approved, modifications will be automatically generated for each site and approved. Sites will be notified 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.

# WU as Reviewing IRB/Single IRB (sIRB)

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## sIRB CONTINUING REVIEWS



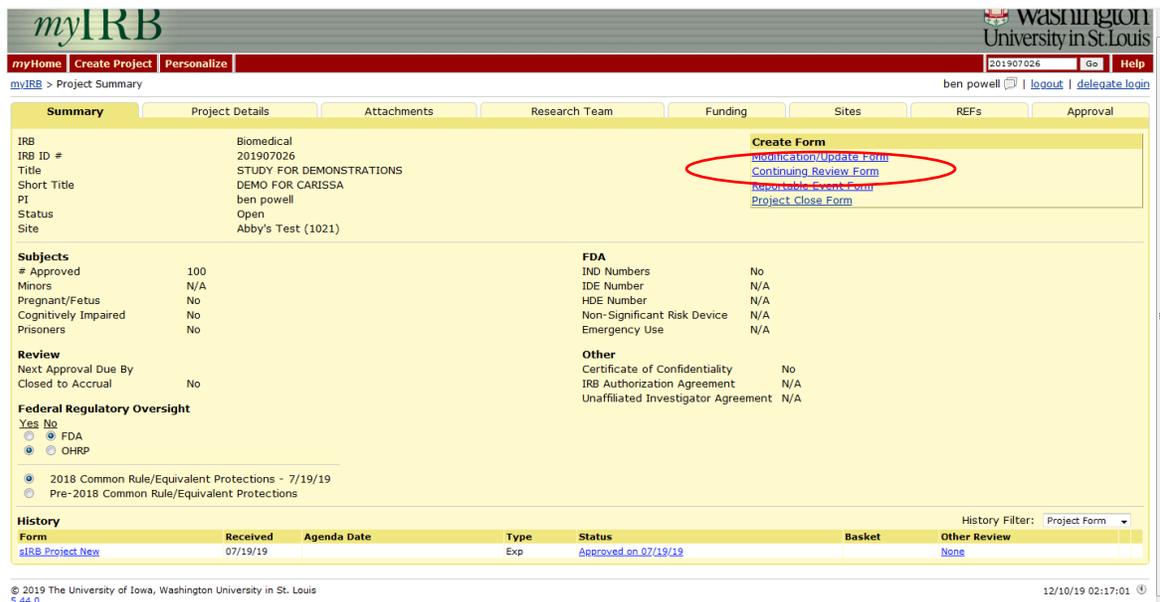
1. The Lead PI will receive a notice when the continuing review of a study is due. The Lead PI will need to log in to myIRB and start the continuing review form.
2. At the end of the form, the Lead PI will click the button generating the site portions of the continuing review forms.
3. The site PIs will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

# WU as Reviewing IRB/Single IRB (sIRB)

## Submitting a Continuing Review

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

1. 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 oval, containing the following links:

- [Modification/Update Form](#)
- [Continuing Review Form](#)
- [Response/Event Form](#)
- [Project Close Form](#)

The 'History' table at the bottom shows a single entry:

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

2. Click on CR 1. Project Summary to start completing the application. Answer the questions in section CR 1 and click Continue/Save to move to additional questions in CR 2.

# WU as Reviewing IRB/Single IRB (sIRB)

3. 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.

The screenshot displays the myIRB web application interface. At the top, the myIRB logo is on the left, and the Washington University in St. Louis logo is on the right. Below the logos is a navigation bar with links for myHome, Create Project, Personalize, and Help. A search bar with the text '201907026' and a Go button is also present. The main content area is titled 'CR 3. Site CR forms' and contains two sections: CR 3.1 and CR 3.2. CR 3.1 is titled 'Date/time when the site Continuing Review forms were created:' and contains the text '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:'. A gray button labeled 'Create Site Continuing Review Forms' is circled in red. CR 3.2 is titled 'Continuing Review forms for the sites associated with this protocol:'. The interface includes navigation buttons such as '<- Back/Save', 'Index/Save', 'Save and Remain', and 'Continue/Save -->'. The footer contains copyright information for 2019 The University of Iowa, Washington University in St. Louis, version 5.44.0, and a timestamp of 12/10/19 02:22:06.

4. If there are attachments that need to be attached, please attach them on the attachment page at the end of the application. Please note, if myIRB is not prompting you to attach anything, no attachments are needed.

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5. 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.

a. You will also need to submit your own Site CR form that will be generated. To complete this, go to the PIs Inbox and click on file folder icon under the TO DO heading.

The screenshot shows the myIRB interface. At the top, there's a navigation bar with 'myHome', 'Create Project', and 'Personalize'. Below that, the user is logged in as 'ben powell'. The main content area is titled 'Inbox - To Do' and contains a table with the following data:

IRB ID #	To Do	Form	IRB Project Title	PI	Current Basket	Previous Basket
201810003-1021	Regular	sIRB Site New	BIO Kidney Project	ben powell	Relying Admin Pending	PI Signature Requested
201809001-1021	Regular	sIRB Site New	BIO In Meeting Test	ben powell	Relying Admin Pending	PI Signature Requested
201901032-1021	Regular	sIRB Site CR	BIO test for prod	ben powell	Protocol CR Pre Submit	

b. Click on CR.1 Project Summary and click Continue/ Save to complete all questions in the application. You do not need to attach any documents.

The screenshot shows the 'Continuing Review Index' page in the myIRB system. The page title is 'test for prod' and 'Continuing Review Index'. Below the title, there are three buttons: 'CR 1', 'CR 2', and 'CR 3', with 'Review & Submit' next to them. The 'CR 1' button is circled in red. Below the buttons, there are three boxes representing the review steps: 'CR 1. Project Summary', 'CR 2. Current Enrollment', and 'CR 3. Progress Report'. The 'CR 1. Project Summary' box is highlighted with a red border.

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- c. Click the route form for signatures button and have the form signed by the PI.
- d. Once all the forms are completed, you will log in, go to the draft forms then to Section CR 3. and see that the site form sections are green and all the signatures have been obtained. You are then able to click continue save and have the form signed by the Lead PI. The Project CR form and all the Site CR forms will be sent to the IRB for review.

The screenshot displays the 'myIRB' interface for Washington University in St. Louis. The main section is titled 'CR 3. Site CR forms'. It lists two sites:

- Abby's Test (1021) PI: ben powell**: Shows 'Signed by Site PI' with a green 'CR 3' button and a 'Non-responsive' checkbox.
- University Of Washington (1003) PI: Jonathan Himmel**: Shows 'Signature Pending' with a red label, a green 'CR 3' button, and a 'Non-responsive' checkbox.

Navigation buttons include '<-- Back/Save', 'Index/Save', 'Save and Remain', and 'Continue/Save -->'.

6. 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.
7. The Project CR and all the site forms will be reviewed together. You will receive an email from myIRB letting you know the CR has been approved or asking that you complete the IRB's required actions.

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## **sIRB REPORTABLE EVENTS**

1. Reportable Events can be submitted at both the Project and Site level.
2. 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 1 site).
3. The WU IRB Reporting Requirements must be followed, sites may also have reporting requirements they must follow locally.

## **sIRB EXCEPTIONS**

1. There is not an exception form available for single IRB applications.
2. If a change is needed to the protocol for a single or a few specific subjects, you will need to submit a protocol modification describing this change.

## **sIRB Closures**

1. PI's are required to submit closure forms in myIRB at the conclusion or discontinuation of all IRB approved projects.
2. Once a site is closed, the site cannot be re-opened. To re-open a project or site a new form must be created and new project or site fees will be charged.
3. Projects or sites should only be closed when:
  - a. All research interventions (e.g. labwork, investigational drug administration, radiology exams) and interactions (e.g. questionnaires, follow up phone calls) with research participants must be completed.
  - b. All planned data analyses conducted by the site investigators should be completed, including data analysis required for pending journal publications.

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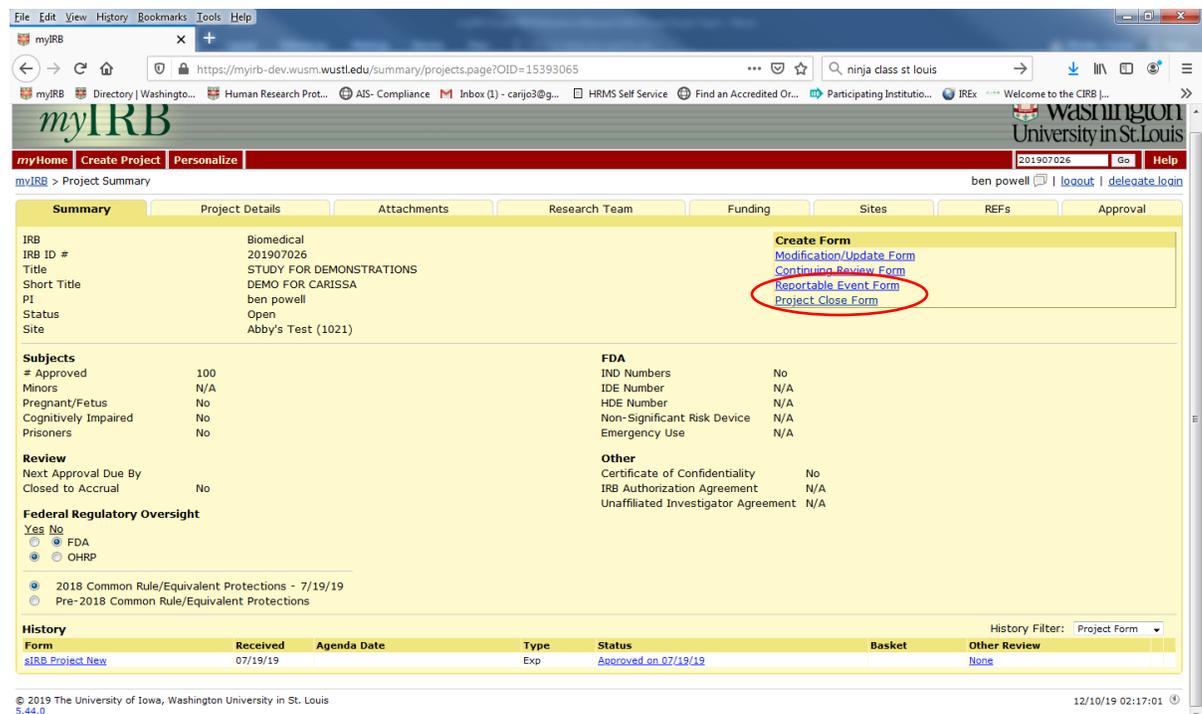
- c. Data cleaning, auditing, and queries from the sponsor/lead site (when applicable) must be completed.
4. Once a closure form is submitted to the IRB the site is automatically closed.

## Submitting a Closure

Only the project PI (or their delegates) can close the Project application. When the project application is closed, all site are automatically closed.

Each site has the ability to close their own site if they need to close prior to the entire project closing.

1. In the Create Form Box, click on Project Close Form or Site Project Close Form.



The screenshot shows the myIRB web application interface. The browser address bar displays the URL: <https://myirb-dev.wustl.edu/summary/projects.page?CID=15393065>. The page header includes the myIRB logo and navigation links: myHome, Create Project, Personalize. The user is logged in as ben powell. The main content area is titled 'Project Summary' and contains several sections:

- Summary:** IRB (Biomedical), IRB ID # (201907026), Title (STUDY FOR DEMONSTRATIONS), Short Title (DEMO FOR CARISSA), PI (ben powell), Status (Open), Site (Abby's Test (1021)).
- Subjects:** # Approved (100), Minors (N/A), Pregnant/Fetus (No), Cognitively Impaired (No), Prisoners (No).
- Review:** Next Approval Due By, Closed to Accrual (No).
- Federal Regulatory Oversight:** Yes/No options for FDA and OHRP, and checkboxes for 2018 Common Rule/Equivalent Protections and Pre-2018 Common Rule/Equivalent Protections.
- History:** A table with columns: Form, Received, Agenda Date, Type, Status, Basket, Other Review. The first row shows 'sIRB Project New' received on 07/19/19, with status 'Exp' and 'Approved on 07/19/19'.

In the 'Create Form' section, the following links are listed: Modification/Update Form, Continuing Review Form, Reportable Event Form, and Project Close Form. The 'Project Close Form' link is circled in red.

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2. Read the prompts and confirm you want to close the study. Provide the information ensuring that you are entering the correct number of subjects and that it is not less than the number of subjects your reported on your last modification or continuing review.

3. Click Submit.

## Appendix: Definitions

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**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.

**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.”

**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.

**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.

**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.

# Appendix: Definitions

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**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) at the Relying Site IRB or research office who will provide local context information by completing the Site Registration and will sign off on Relying Admin forms in myIRB on a study by study basis. This person is not typically on the study team and must be someone with the authority to agree to defer to the WU IRB on a study by study basis.

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

**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.

## Sources:

SMART IRB Agreement