This Guide will help me to know?
- How to submit an external IRB study
- How to locate an external IRB study or site
- How to make changes to an external IRB study
- How to close an external IRB study

What’s new for external IRB studies in Click IRB?
- The external IRB process in Click is different than the previous version of Click IRB to accommodate the single IRB (sIRB) NIH Policy that became effective in 2018.
- Updates to the types of information being collected about external IRB studies
- New workflow diagrams for external IRB study/site
- New steps for updating your external IRB study/site
- Continuing review reminders for external IRB studies
- Contact the IRB office if you need further assistance
- New Terminology

<table>
<thead>
<tr>
<th>Term</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>sIRB</td>
<td>Single/External IRB of record; in this guide sIRB will be called “external IRB”</td>
</tr>
<tr>
<td>pSite</td>
<td>Participating site in the IRB study; in this guide Seattle Children’s is the pSite</td>
</tr>
<tr>
<td>Study SmartForms</td>
<td>Set of forms that collects information about the Study</td>
</tr>
<tr>
<td>Site SmartForms</td>
<td>Set of forms that collects information about the pSite(s) involved in a study</td>
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Why do I need to submit external IRB studies to Seattle Children’s IRB?
- External IRB studies must be entered into the Seattle Children’s Click IRB system for tracking purposes
- Institutional systems (e.g. RSAS) may rely upon this data, which if not provided and kept current may cause issues for the conduct of your study.

Under which circumstances do I submit an external IRB study?
- Seattle Children’s is conducting human subjects research that will be relying on any external IRB, including IRBs from local sister institutions [e.g. University of Washington (UW) and Fred Hutchinson Cancer Research Center (Fred Hutch)]

How to submit an External IRB Study in Click IRB
- Visit the external IRB webpage prior to submitting an external IRB study in Click IRB
- Follow the steps outlined in this Reference Guide
Click IRB Reference Guide
External IRB Studies

Submitting a New External IRB study

- Note this section is for entering NEW external IRB studies and not for studies that already exist in Click. Information about how to update/close existing external IRB studies is found later in this guide.

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<th>Action</th>
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| 1.   | Request a **consult** with the **IRB/HSPP Office**. This is a key step to determine if Seattle Children’s is willing to rely on the external IRB that you are proposing.  
  **Exceptions**: Consults are not required if the external IRB is Western Institutional Review Board (WIRB), PedCIRB (National Cancer Institute), Advarra, or the University of Washington. |
| 2.   | Create External IRB **Study** Record  
  - Navigate to the Click IRB Module (see the Navigating Click IRB Quick Guide on the **Click IRB Resources Page** for instructions).  
  - Click **Create New Study**. This will open up a new **Study** SmartForm. |
| 3.   | Complete the **Study Basic Information** SmartForm (Screen shot on next page)  
  - Respond **Yes** to question 5 regarding an external IRB  
  - **Tip**: Choose carefully, once you continue to the next page in the Study SmartForm, you are committed to an external IRB submission and cannot change the study back to a Seattle Children’s IRB submission  
  - **Question 4**: Use the local Seattle Children’s PI here because Click will not have the name of the external PI.  
  - **Question 7**: Protocols are now required for all external IRB studies in Question 7. |
Click IRB Reference Guide
External IRB Studies

Basic Information

1. Title of study:
   2018.09.07 Polek Test External IRB Study

2. Short title:
   2018.09.07 Polek Test External IRB Study

3. Brief description:
   2018.09.07 Polek Test External IRB Study

4. Principal investigator:
   Tara Polek

5. Will an external IRB act as the IRB of record for this study?
   - Yes
   - No

6. What kind of study is this?
   - Multi-site study (More than one site will conduct the entire study)
   - Collaborative study (each site will conduct a portion of the study)
   - Single-site study

7. Attach the protocol: (Templates available in the Library)
   - Add

Choose the best option; the choice made here once you select "yes" in question 5 will not change the workflow.

Attaching the protocol is required for all external IRBs.
4. Complete the **Study External IRB** SmartForm:

- **Question 1**: Identify your external IRB
  - “PedCIRB” will appear as “National Cancer Institute”
  - If the External IRB is not in the list, follow instructions in the help text. Additionally, submit HRP-815 Institutional Profiles (in Click IRB Library Templates Tab) to the IRB inbox when you request addition of the new External IRB.

- **Questions 3-5**: Provide the approval letter and information, if available
  - **NEW!!** External IRB studies may receive continuing review reminders based on the date that you have entered in Question 5. These are a courtesy reminders that you will need to update your approval letter (Question 3) and the last day of approval period (Question 5) after the external IRB has completed their continuing review. More information about this [here](#).

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**Examples of responses:**

- This is a study where the Sponsor is using WIRB, Advarra, PedCIRB, etc
- SCRI has limited engagement in this study
5. Complete the **Study Funding Sources** SmartForm:

**Tips:**
- Add funding information on the study level (e.g. held by the Sponsor/Institution who is overseeing the overall study; do not add funding that is only held by the pSite (e.g. Seattle Children’s); this funding will be added later to the **Site** Funding SmartForm
- Pay attention to the help text for this question that explains what “Direct Funding Source” and “Originating Funding Source” means

6. Complete the **Study Scope** SmartForm: Add study drugs or devices

- This SmartForm is relatively new for external IRB studies; however, this SmartForm is the same as for Seattle Children’s reviewed studies
- Choosing yes will reveal SmartForm pages for drugs or devices that will need to be completed
7. Complete the **Study** Related Documents SmartForm

- **Question 1** Consent forms: Attach template versions from the Sponsor here, if available.
- **Question 2** Recruitment materials: Attach template versions from the Sponsor here, if available

**Tip**: Questions 1 and 2: These forms are NOT required for WIRB, PedCIRB (National Cancer Institute), Advarra studies

- **Question 3** Other Attachments: Generally nothing will be attached here

**Study-Related Documents**

1. **Consent form templates**: (include an HHS-approved sample consent document, if applicable)
   - Add Sponsor templates here unless WIRB, PedCIRB, Advarra

2. **Recruitment material templates**: (add templates for all material to be seen or heard by subjects, including ads)
   - Add Sponsor templates here unless WIRB, PedCIRB, Advarra

3. **Other attachments**:
   - There are no items to display
8. On Final Page of Study SmartForms, click **Save and Close**
   - Clicking **Save and Close** returns you to the **Study** Workspace
   - You can precede this step with “Hide/Show Errors” to find required questions that have been missed
   - **Important!** Note there will **NOT** be a Submit button on the next page for external IRB studies; you will need to continue completing steps outlined in the reliable method to fill in your **Site** SmartForms.

   **Final Page**

   You have reached the end of the IRB submission form. Read the next steps carefully:

   1. Click **Save and Close** to exit the form.
   2. **Important!** To send the submission for review, click **Submit** on the next page.

9. Observe the Workflow Diagram for your External IRB **Study**
   - Note that your **Study** has only two states: “External IRB” or “Closed”
   - The Workflow will remain as “External IRB” until the study is closed.
   - You are able to edit the **Study** SmartForms when the external IRB communicates changes to your study team; more information about this is covered **later** in this guide.

   **STUDY00006799: 2018.09.25 Test External IRB**

   Lead principal investigator: PI NI
   Local site: SITE00000002

   External IRB: WIRB
   Study Codes: 
   External IRB approval letter: 
   Regulatory authority: Pre-2018 Requirements
10. Navigate to Site Workspace from the Study Workspace

- Notice a new link has been created on the Study Workspace for a Site Workspace; the Site workspace/SmartForms capture information about the pSite (e.g. Seattle Children’s for external IRB studies).
- Clicking on Local Site will move you to the Site Workspace where you will complete your Site SmartForms to complete your submission.
- **Important!** If you only fill in the Study SmartForm and not the Site SmartForm, your submission is not complete; you must complete both sets of SmartForms before submitting to the pSite IRB.
11. Fill in the Site SmartForms
   - Click “Edit Site” to enter the Site SmartForms

12. Complete the Site Basic Information SmartForm
13. Complete the **Site** Funding SmartForm

**Tips:**
- Add funding information on the **pSite** level (e.g. held by Seattle Children’s only); do not add funding that is only held by the Sponsor/Institution for the study overall because this funding should only appear on the **Study** SmartForm.
- Pay attention to the help text for this question that explains what “Direct Funding Source” and “Originating Funding Source” means.
- Generally there is no **Site** specific funding, thus this page will frequently not require any information.

14. Complete the **Site** Study Team Members SmartForm:
- Enter the entire study team on the Study Team Member page of the **Site** SmartForm.
- Enter team members that are acting as agents of Seattle Children’s IRB.
- Do not enter external Team Members here unless instructed by IRB coordinator. Reliance agreements cover Seattle Children’s engagement in a research study and do not cover engagement of outside institutions (including UW and Fred Hutch).
- You can assign a PI Proxy if desired. See the PI Proxy Quick Guide on the **Click IRB Resources Page**.
15. Complete the **Site Research Locations** SmartForm:

**Tip:** Pay attention to the help text for the question in order to provide the correct information; this question is NOT asking for other participating sites (pSites)

**Research Locations**

1. Identify other research locations where the investigators will conduct research.

   - Add

<table>
<thead>
<tr>
<th>Location</th>
<th>Contact</th>
<th>Phone</th>
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<tbody>
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</table>

   There are no items to display.

Add Research Locations here; pay attention to the information in the help text.

16. Complete the **Site Local Site Documents** SmartForm:

   - This page is for documents that will be used at Seattle Children’s (i.e. not for Sponsor template documents)

     - **Question 1 Consent forms:** Attach Seattle Children’s versions of consent documents here unless the IRB of record is WIRB, PedCIRB (National Cancer Institute), Advarra
     - **Question 2 Recruitment materials:** Attach Seattle Children’s version of recruitment materials: unless the IRB of record is WIRB, PedCIRB (National Cancer Institute), Advarra
     - **Question 3 Other Attachments:**
       - If the external IRB is WIRB, PedCIRB (National Cancer Institute), Advarra: attach the coversheet here
       - For other external IRBs, attach the executed agreement (note the agreement can be partially executed as long as Seattle Children’s has signed off). Attach any other reliance documents here (HRP-815 Institutional Profile, etc.)

**Local Site Documents**

1. **Consent forms:** (include consent, parental permission, and assent forms, if applicable; templates available in the Library)

   - Add

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

   There are no items to display.

   **Attach Seattle Children’s consents here unless WIRB, PedCIRB, Advarra**

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads)

   - Add

<table>
<thead>
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   There are no items to display.

   **Attach Seattle Children’s recruitment documents here unless WIRB, PedCIRB, Advarra**

3. **Other attachments:**

   - Add

<table>
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</tbody>
</table>

   There are no items to display.

   **Attach agreements, cover sheets, other reliance documents here**
17. **On Final Page of Site SmartForms, click **Save and Close**
   - Clicking Save and Close returns you to the Site Workspace
   - You can precede this step with “Hide/Show Errors” to find required questions that have been missed

**Final Page**

You have reached the end of the IRB submission form. Read the next steps carefully:

1. **Click Save and Close** to exit the form.

2. **Important!** To send the submission for review, click **Submit** on the next page.

18. **Submit the Site to Seattle Children’s IRB:**
   - Have the PI or PI Proxy click the “Submit” link under “Next Steps”. Note only the PI or PI proxy will be able to see the submit link.
19. Verify that the Site Submission has been submitted to Seattle Children’s IRB
   - The Pre-Review oval of the Workflow Diagram should be colored in Orange
   - When an IRB coordinator is assigned to your study, his/her name will appear as “IRB coordinator”
20. Remainder of the journey through the External IRB Site Workflow

SITE00000662: Site for 2018.09.25 Test External IRB

1. Clarification Requested: IRB coordinator may request information from your study team that you will need to supply and submit your response back to him/her

2. Pending sIRB Review:
   a. You can expect a letter where Seattle Children’s has acknowledged your request to use an external IRB.
   b. You can make edits to the Site SmartForm during the Pending sIRB Review state if the external IRB has requested edits to your information/documents
   c. New! When the external IRB has rendered their decision, Click on a new activity called “Correspond or Update Seattle Childrens IRB” under the Next Steps Menu. Enter a message to the IRB that the Site has completed external (sIRB) review and is ready for the decision to be recorded

3. Post-Review: The IRB coordinator has recorded the external IRB’s decision.

4. Modifications Required: The external IRB has requested changes to the Site submission; the IRB Coordinator may communicate the changes requested and the study team can edit the Site submission accordingly; this is not a common step in the workflow.

5. Review Complete:
   a. Your Site has been approved by the external IRB and this decision has been recorded by the Seattle Children’s IRB; the Seattle Children’s pSite is approved.
   b. You can expect a letter indicating that your Site has been approved.
How to locate your External IRB Study or Site

Remember that your external IRB study is composed of two parts: the Study Submission and the Site Submission. In order to make edits or view these different parts, you will need to know where to locate them.

How to locate an external IRB Study: An external IRB study has an ID number that starts with STUDY or PIROSTUDY (for legacy external IRB studies).

1. Log into Click IRB and Navigate to the IRB module by clicking “IRB” in the blue navigation bar
2. Click the External IRB Studies Tab
3. Use the Filter to search for your external IRB Study

How to locate an external IRB Site: A site for an multi-site or external IRB study has an ID number that starts with SITE.

1. Log into Click IRB and Navigate to the IRB module by clicking “IRB” in the blue navigation bar
2. Click the Sites Tab
3. Use the Filter to search for your Site
How to make changes to an external IRB study

- Remember that your external IRB study is composed of two parts: the Study Submission and the Site Submission; updates to each part differ and are explained below.
- In the older version of Click IRB, changes to External IRB studies were called “Updates”; in the 8.1.4 version of Click IRB, there is new terminology:
  - Changes to the Study will not generate a new transaction; study teams can edit the Study at any time without requiring action from the Seattle Children’s IRB
  - Changes to the Site will be completed via a Site Modification. The transaction will be referred to as a Modification (MOD) and will no longer be called an Update (UPDAT)

How to edit your Study SmartForms

1. Log in to Click IRB, click on IRB tab, find and select the appropriate external IRB Study to be updated, and click on Edit Study under Next Steps on the left side of the screen.
2. Edit the information in the Study SmartForms as necessary
   • Information in the external IRB SmartForms should be updated when it changes.

   **Tips:**
   • More information about filling in Study Smart Forms [here](#).
   • Question 5 of the Basic Information form cannot be edited because once you choose external IRB, you are committed to an external IRB set of SmartForms. If Seattle Children’s is no longer going to rely on an external IRB you will need to close out this study and submit a new study in Click.

   **Special Notes:**
   • Question 5 of the External IRB SmartForm asks for the “last day of approval period”. This wording is important to understand.
     o For example: study was approved on May 2, 2018 and received a one year approval period, the “last day of approval period” is May 1, 2019 (one year minus one day). On May 1, 2019 is still approved. On May 2, 2019, the study would be expired/lapsed if it was not re-approved by the IRB.
   • Institutional systems downstream from the IRB (e.g. RSAS) may rely upon this data, which if not provided and updated, may cause issues for the conduct of your study.
   • **NEW!!!** External IRB studies may receive continuing review reminders in Click and your Outlook via a Click notification based on the date that you have entered in Question 5. These are a courtesy reminders that you will need to update your approval letter (Question 3) and the last day of approval period (Question 5) when the external IRB has completed their continuing review.

3. Your Study changes are now complete

   **Special Notes:**
   • The IRB is not notified by the system that you have made edits to the Study SmartForm; **Optional**: If you have a reason to notify the IRB about changes you have made to the Study record, use the “Correspond or Update Seattle Childrens IRB” under the Next Steps Menu on the Site record.
How to submit a modification to your Site SmartForms

1. Log in to Click IRB, click on IRB tab, find and select the appropriate Site to be updated, and click on Create Modification under Next Steps on the left side of the screen.

2. Fill out the Modification SmartForm
   1. Choose “Modification”
   2. Select the scope of the modification
      - Special Note: If you choose “Other parts of the site”, your modification will require an extra communication loop for review by the external IRB; if you are only modifying the study team or research location, then only select the “Study team and research location information” box which will give you a shorter workflow
3. Fill out the Modification Information SmartForm

**Tips:** Question 3: only include changes you made to the Site record, not the Study record.

```plaintext
Modification Information

1. Study enrollment status:
   - ☐ No subjects have been enrolled to date
   - ☐ Subjects are currently enrolled
   - ☐ Study is permanently closed to enrollment
   - ☐ All subjects have completed all study-related interventions
   - ☐ Collection of private identifiable information is complete

2. Notification of subjects: (check all that apply)
   - ☐ Current subjects will be notified of these changes
   - ☐ Former subjects will be notified of these changes

3. *Summarize the modifications:* [Help]
   - Include only the changes you are making to the Site record

4. Update the Site SmartForms as applicable; Click Save and Close when finished.

**Tips:**
- Also update the Study record before submitting in the next step (usually this would include the External IRB SmartForm, Questions 3 and 5).
- Navigate [here](#) for more information about filling in the Site Smart Forms correctly.
- You do not need to update consent forms or recruitment materials (either templates on the Study record or Seattle Children’s versions) when the external IRB has approved changes.
5. Submit the Site modification to Seattle Children’s IRB:
   - Have the PI or PI Proxy click the “Submit” link under “Next Steps”. Note only the PI or PI proxy will be able to see the Submit link.
6. Remainder of the journey through the External IRB Site Modification Workflow

1. **Clarification Requested:** IRB coordinator may request information from your study team that you will need to supply and submit your response back to him/her

2. **Pending sIRB Review:**
   a. The submission is under review by the external IRB;
   b. You can make edits to the Site SmartForm during the Pending sIRB Review state if the external IRB has requested edits to your information/documents
   c. **New!** When the external IRB has rendered their decision, Click on a new activity called “Correspond or Update Seattle Childrens IRB” under the Next Steps Menu. Enter a message that the Site modification has completed external (sIRB) review and is ready for the decision to be recorded.

3. **Post-Review:** The IRB coordinator has recorded the external IRB’s decision.

4. **Modifications Required:** The external IRB has requested changes to the Site modification submission; the IRB Coordinator may communicate the changes requested and the study team can edit the Site modification submission accordingly; this is not a common step in the workflow.

5. **Review Complete:** Your Site modification has been approved by the external IRB and this has been recorded by the Seattle Children’s IRB. You can expect a letter indicating that your Site has been approved.
How to request closure of your external IRB study and site

1. **Important!** Confirm that you really wish to close the External IRB study; A closure cannot be “undone” in Click IRB. If you are sure you wish to close the study, proceed to the next step.

2. **Navigate to the** Study Workspace
   - Find information [here](#) about navigating to your External IRBs.

3. **Update the External IRB SmartForm on the** Study Workspace
   - Question 3: Attach the closure letter
   - Question 5: Update the last day of approval for the external IRB study; Ideally this is the date the external IRB has closed the study; however, Click will not allow you to enter a past date so enter the current date if necessary

4. **Click on Correspond or Update Seattle Children’s IRB Office**
   **New!** When you wish to close your external IRB study; click on a new activity called “Correspond or Update Seattle Childrens IRB” under the Next Steps Menu. Enter a message to the Seattle Children’s IRB that you wish to close your external IRB study.
5. Verify Closure of the Study and Site

The IRB Staff will review your request to close the Study and will administratively close it for you. After you receive a notification from Click IRB that the study has been closed, you should verify closure of the external IRB study.

- Notice the Study state appears as “Closed” in the upper left of the Study workspace and the Workflow diagram shows the Study in a “Closed” state.

- Notice the Site state appears as “Closed” in the upper left of the Site workspace.

More questions? Contact the Institutional Review Board by email or at x77804.