What’s new for external IRB studies in Click IRB?

- In the latest upgrade, users will notice that the external IRB process in Click has undergone a substantial makeover compared to the previous version of Click IRB. The changes were made to accommodate the single IRB (sIRB) NIH Policy that became effective in 2018.
- New Terminology
  - sIRB=Single/External IRB of record; in the case of an external IRB study, the external IRB is the sIRB; in this Quick Guide the sIRB will be referred to as the external IRB.
  - pSite=Participating site in the IRB study; in the case of an external IRB study, SCRI is the pSite
  - Study SmartForm=set of forms that collects information about the study
  - Site SmartForm=set of forms that collects information relevant to the pSite(s) involved in a study
- Updates to the types of information being collected about external IRB studies
- New workflow diagrams for external IRB studies
- New steps for updating your external IRB study/site
- Contact the IRB office if you need further assistance

Why do I need to submit external IRB studies to Seattle Children’s IRB?

- Data for external IRB studies must be entered into Seattle Children’s Click IRB system for tracking purposes
- Institutional systems downstream from the IRB (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 our local sister institutions such as 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 Quick Guide
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.

<table>
<thead>
<tr>
<th>Step</th>
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<tr>
<td>1.</td>
<td>Request a <strong>consult</strong> with the <strong>IRB/HSPP Office</strong>. This is a key step to determine if Seattle Children’s can function as the sIRB for your study.</td>
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</table>
| 2.   | Create Multisite IRB **Study** Record  
  - Navigate to the Click IRB Module (see the Navigating Click IRB Quick Guide for instructions).  
  - Click **Create New Study**. This will open up a new **Study** SmartForm. |
| 3.   | Complete **Study Basic Information** SmartForm  
  - Respond **No** to question 5 regarding an external IRB  
  - Check **Yes** to Question 6  
  **Tips:**  
  - Choose carefully, once you continue to the next page in the Study SmartForm, you are committed to an external IRB submission and cannot change it back to a local IRB submission  
  - **NEW!!!** Protocols are now required for all external IRB studies  
  - **NEW!!!** You will need to have the external PI entered into the Click system by submitting an IS ticket to put in a request to have him or her added.  
    - For more information about submitting an IS ticket, see the Changing Email Preferences Click IRB Reference Guide here: [https://www.seattlechildrens.org/research/resources/institutional-review-board/click-irb-resources/](https://www.seattlechildrens.org/research/resources/institutional-review-board/click-irb-resources/)  
    - You can add the Seattle Children’s PI as a “placeholder” until the IS ticket to add the external PI is resolved |
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
   - Clear

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)
   
   [Table with columns for Document and Category]

   There are no items to display

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- Submit an IS ticket to have the external PI added to select here
- 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 Study External IRB SmartForm:
   - **Question 1**: Identify your external IRB. “CIRB” will appear as “National Cancer Institute”. If the External IRB is not in the list, follow instructions in the help text.
   - **Questions 3-5**: Provide the approval letter and information, if available.
   - **Questions 7-12**: **Important!**: Study team should leave these questions blank

![External IRB SmartForm](image)

**Reasons could include:**
- This is a CIRB Sponsored Study
- This is a study where the Sponsor is using WIRB
5. Complete **Study Funding Sources** SmartForm:

**Tip:** add funding information on the study level (e.g. held by the Sponsor/Institution who is overseeing the 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 SmartForms

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

- This SmartForm is new for external IRB studies; however, this SmartForm is the same as for SCRI reviewed studies
- Choosing yes will reveal SmartForm pages for drugs or devices that will need to be completed
7. Complete the Study Related Documents Page
   - **Question 1** Consent forms: Attach template/approved versions from the Sponsor here if available.
   - **Question 2** Recruitment materials: only attach template recruitment materials if directed by the IRB Coordinator during pre-review
   - **Question 3** Other Attachments: Generally nothing will be attached here
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.
10. Navigate to Site Workspace from the Study Workspace

- Notice a new link has been created on the Study Workspace to a Site Workspace; the Site workspace/SmartForms captures 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 **Site** SmartForms
   - Click “Edit Site” to enter the **Site** SmartForms

12. Complete **Site** Basic Information SmartForm

   - Title of site:
     Site for 8.29.18 Polek Test External Study
   - Short title:
     Site for 8.29.18 Polek Test External Study
   - Brief description:
     8.29.18 Polek Test External Study
   - Principal investigator:
     This is the local PI (e.g. from Seattle Children’s)
13. Complete 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.
- Often there is no Site specific funding, thus this page will frequently not require any information.

14. Complete 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 **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)

16. Complete **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 consenting documents here
  - Question 2 Recruitment materials: only attach template recruitment materials if directed by the IRB Coordinator during pre-review
  - Question 3 Other Attachments: Unless this is a CIRB or WIRB study, attach the executed IAA or coversheet here; note the IAA can be partially executed as long as Seattle Children’s has signed off. Note you should update the partially executed document with the fully executed IAA when it is available. See information about how to update the IAA [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

**Principal investigator:** PI Ni  
**Submission type:** IRB Site  
**Primary contact:** PI Ni  
**PI proxies:**

#### Pre-Submission

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. **Important!** When the external IRB has rendered their decision send an email to 
      [irb@seattlechildrens.org](mailto:irb@seattlechildrens.org) with the following information:
      i. Site identification number
      ii. External IRB Study identification number
      iii. Name of assigned IRB coordinator (if assigned)
      iv. Information that the Site has completed sIRB review and is ready for the sIRB decision to be recorded.
   d. Once the IRB receives your information, an IRB Coordinator can record the external IRB’s decision.

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.

5. **Review Complete:** Your Site has been approved by the external IRB and this decision has been recorded by the Seattle Children’s IRB.
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 a 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
Click IRB Reference Guide
External IRB Studies

How to update or close 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 to be familiar with:
  - 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
   - Any of the information in the external IRB SmartForms should be updated when it changes.

   **Tips:**
   - More information about filling in Study Smart Forms [here](#).
   - Do not add information to questions 7-12 on the External IRB SmartForm.
   - 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.
     - 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.

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 that you like to notify the IRB about changes you have made, email [irb@seattlechildrens.org](mailto:irb@seattlechildrens.org) with the following information:
     - External IRB Study identification number
     - Name of assigned IRB coordinator (if assigned)
     - Any information that you wish to convey about changes you have made to the Study 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
3. Fill out the Modification Information SmartForm

*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:**

   Provide a comprehensive summary of proposed changes

4. Update the Site SmartForms as applicable; Click Save and Close when finished.
   **Tip:** navigate [here](#) for more information about filling in the Site Smart Forms correctly.

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.
Click IRB Reference Guide
External IRB Studies
External IRB Studies

6.余下的旅程通过外部IRB站点修改工作流

1. **澄清请求**：IRB协调员可能会要求您的研究团队提供您需要提供的信息，并将您的回复反馈给他/她。

2. **待sIRB审查**
   a. 该提交正在由外部IRB审查；
   b. 您可以在待sIRB审查状态下编辑SmartForm，如果外部IRB要求您编辑您的信息/文件。
   c. **重要！**当外部IRB做出决定时，请通过电子邮件将以下信息发送至irb@seattlechildrens.org：
      i. 网站修改标识号
      ii. 外部IRB研究标识号
      iii. 指定IRB协调员的姓名（如果指定）
      iv. 信息，说明网站修改已完成sIRB审查，并已准备好记录sIRB决定。

3. **审查后**：IRB协调员已记录外部IRB的决定。

4. **修改所需**：外部IRB已要求对您网站的修改提交进行更改；IRB协调员可能会通知您更改请求，研究团队可以相应地编辑网站修改提交。

5. **审查完成**：您的网站修改已由外部IRB批准，并已记录由Seattle Children's IRB。
How to request closure of your external IRB study

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 for External IRBs.

3. **Send an email to** [irb@seattlechildrens.org](mailto:irb@seattlechildrens.org). Include the following information:
   - External IRB **Study** identification number
   - Name of assigned IRB coordinator (if assigned)
   - Indicate that you wish to close the Study
4. The IRB Staff will review your request to close the Study and will administratively close it for you. You can verify closure in the Study Workflow diagram. Notice the Study state appears as “Closed” in the upper left of the Study workspace and the Workflow diagram shows as “Closed”.

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