Click IRB Quick Guide
External IRB Studies

If you are using an External IRB, a new study must be created for it in Click IRB. Legacy External IRB studies have already been migrated to Click. Both Click initiated and Legacy IRBs should be updated with new information or closed when the study has been completed. Institutional systems downstream from the IRB (e.g. RSAS) may rely upon this data, which if not provided, may cause issues for the conduct of your study.

How to submit a new external IRB study

1. Request a consult with the IRB/HSPP Office, unless submitting to NCI CIRB or WIRB.
   Note this section is for NEW external IRB studies and not for studies that already exist in Click (e.g. migrated Legacy studies). Information about how to update/close External IRB studies is found later in this guide.

2. Unless this is a CIRB or WIRB study, obtain an IRB Authorization Agreement signed by both institutions.

3. Log in to Click IRB, click on My Inbox, and click on Create New Study.

Links by Solution
- Financial Disclosures
- IRB
  - My Current Actions
    - Create New Study
    - Report New Information
- Submissions
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Basic Information SmartForm: respond Yes to question 5 regarding an external IRB.

- **Title of study:**
  - Test of External IRB 7.12.16

- **Short title:**
  - External IRB Test 7.12.16

- **Brief description:**
  - testing external IRB

- **Principal investigator:**
  - AutomationPI NW

- **Will an external IRB act as the IRB of record for this study?**
  - Yes

Check yes to question 5, then question 6 will disappear
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.
- **Question 2**: Attach the fully signed IRB Authorization Agreement, if available.
- **Questions 3-5**: Provide the approval letter and information, if available.

**Tip**: For Questions 2-5: Note you may have to submit an update to the study to add the dates later if they are not available. Instructions to update External IRB studies are found later in this guide.

Funding Sources SmartForm: add funding information

**Note that if your organization is not listed, please see help text for how to get it added.**
7. **Study Team Members** SmartForm:
   - Enter the entire study team on the Study Team Member page of the SmartForm.
   - You can assign a PI Proxy if desired. See the [PI Proxy Quick Guide](#) on the [Click IRB Resources Page](#).

8. **Supporting Documents** SmartForm: attach supporting documents, if applicable
   - For NCI CIRB or WIRB studies, attach relevant documentation (e.g., cover sheet/intent to open form).
   - For CIRB studies attach a Legacy HIPAA form as you did for legacy external IRB studies.

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You should attach your cover sheets/intent to open forms and HIPAA forms here.
Click the **Submit** button

- An HSPP Analyst will receive your submission and confirm use of the selected external IRB. In general, no letter will be generated when the IRB confirms use of an External IRB. However you can see that use of the External IRB was approved by looking at the Workflow Diagram:

- Pay attention to any comments that the analyst posts when your external IRB is confirmed
How to update or close an external IRB study

1. Log in to Click IRB, click on **IRB tab**, find and select the appropriate external IRB study to be updated or closed, and click on **Update Study** under **My Current Actions** on the left side of the screen.

   - Any of the information in the external IRB SmartForms should be updated when it changes.
   - Updates could include (but are not limited to): changes in study approval dates; PI or other study team members, funding information, or supporting documents, study title or brief description.
   - Changes to the study reviewed by an External IRB only need to be updated if impacts the approval dates or other SmartForm fields.
   - **Special Note:** Institutional systems downstream from the IRB (e.g. RSAS) may rely upon this data, which if not provided, may cause issues for the conduct of your study.

   ![My Current Actions](image)

2. Add a summary of the proposed changes

   ![Study Update Information](image)

   **Add information about what you are changing:** For example, updating the approval date.
Update Smart Form Fields/Attachments: Any of the SmartForm pages should be edited if the information has changed in that form. Pay special attention to making sure the Funding SmartForm is filled in with appropriate information if your study has funding.

For guidance, see the information above regarding “How to submit a new external IRB study”.
- For legacy IRB studies, you do not have to re-create your legacy documents/information in the SmartForm, unless you are making revisions.

To update your approval dates, edit the External IRB Page:
- **Question 3**: Add the most recent initial approval or re-approval letter. This could be the letter where Seattle Children’s was added to the study or the latest Continuing Review approval letter.
- **Questions 4**: The initial approval date should not be updated unless there is an error.
- **Question 5**: The “last day of approval period” in this letter should match the date in the letter attached to Question 3.
- **Question 7**: Only check “yes” if the External IRB has closed the study.

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