GETTING STARTED

Q: How do I obtain access to Click IRB?

A: Click eIRB accounts can be requested by clicking the “Request Account” link at https://eirb.providence.org. When you request access, please include in the free text section the reason for access, your role, and a contact number. This will help expedite your request.

Q: How do I log in to the Click IRB system?

A: Here’s the address for the login window for Click eIRB: https://eirb.providence.org
- Internal user log-in: Use the “Caregivers” login on the left to sign in via Providence Health & Services Single Sign-On (SSO).
- External user log-in (those outside of Swedish/Providence): Use the ‘External Partners’ login on the right (requires a user name and password).

Q: Do I need Click training?

A: Training is strongly recommended before you begin. The Click system is intuitive but training will help your user experience. The shift from iRIS to Click includes changes in business processes and shifts in responsibility. Contact the Swedish Institutional Review Office (IRO) at 206-215-2536 to schedule training. We offer in-person training, online training and group training. A Study Submission Guide is also available in Click or from the IRO.

Q: Can I keep using iRIS?

A: Submissions to iRIS are no longer accepted. However, study legacy documentation (protocols, consent forms, etc) is still available for viewing and downloading from iRIS.

Q: Why am I getting messages from Click?

A: PIs, PI Proxies (designated staff who can submit on behalf of the PI), and Primary Contacts will receive email notifications related to these activities:
- Notifications that an item needs sign-off and submission
- Reminders at 90, 60, and 30 days before expiration of study approval
- Notification when study approval has lapsed (please note that if study approval lapses, you will need to re-submit the study as new research)
- Requests for clarification or modifications required to secure approval for any submission
- New comments were logged into the system
- Determination letters sent by the IRB staff

Q: Is my study number changing?

A: Yes, existing IRB study numbers (iRIS legacy studies) are folded into the new Click Number as SWD<IR #>S-<year of submission>. For example, IR #1234S-14 will be SWD1234S-14 in Click.

New studies that didn’t migrate from iRIS to Click will appear as STUDY<year of submission>sequence number, i.e. STUDY2017000001.
Q: How do I find my study?

A: When you log in to Click, your home page will appear. This is what is called your ‘dashboard’. Click on the ‘IRB’ tab in the upper left corner.

- Click on the ‘Active’ tab in the middle of the page.
- Search by study ID number.
- When the study appears, click on the study name. This will take you into the main study workspace.

Q: Has all of my study information migrated from iRIS to Click?

A. Basic study information was pulled into Click from iRIS, but not the supporting documentation for the study (protocols, consents, etc). It’s very important to submit what is called a ‘migration modification’ for your study with clean copies of the protocol, consent form and any patient-facing documents prior to submitting anything else. This will enable you to update the study information (including study staff), assign proxies and provide the most current study documentation, which will then be pulled in automatically at the time of the next continuing review. For instructions on completing a migration modification, please contact the Swedish Institutional Review Office for a Migration Modification Reference Sheet.

Q: Where can forms or templates be found in Click?


Q: I can’t find my funding agency (sponsor) in funding list in Click. How can I get it added?

A: To add an organization to the funding list in Click IRB, contact the support team at ORPOPeResearchSupport@providence.org or submit a service request at http://servicecatalog.providence.org/usm/wpf?Node=icguinode.catalogbrowse

Q: I can’t find my external IRB in Click. How can I get it added?

A: Before submitting an external IRB study, contact the local IRB office at review.board@swedish.org to confirm that agreements are in place to accept the oversight of the external IRB. The local IRB will then have the Click support team add the external IRB to Click.

Q: When preparing to submit an initial (new) study, if I click ‘back’ or ‘exit’ and did not hit ‘save’, will I lose edits?

A: You’ll get a prompt that prevents the Click system from losing your edits. However, it is highly recommended you save frequently as you work in Click.

MANAGING YOUR STUDY DATA

Q: Who has access to the study in Click IRB?

A: To view study information, you must be a part of the study team in Click. Initially, for studies imported into Click IRB from iRIS, only the PI and the Primary Contact will have access to the study until a migration modification is submitted to add other members of the study team.
Q: How do I add external study key personnel to the list of study team members?

A: Use the “External Team Member” section of the Click SmartForm page to add them. Read the help text for the question and follow the instructions.

Q: How is a “PI Proxy” designated to take action on behalf of the PI?

A: Assigning a PI Proxy in Click IRB delegates authority to one or more alternate people on the study team who can then submit new studies and updates to existing studies in Click IRB on behalf of the PI. It is recommended that the designation of a proxy be documented in writing in the PI’s records.

If your study was migrated from iRIS, initially only the PI/Proxy will have access to it in Click. In order to assign a PI Proxy, the PI must first add all study team members to the study record in Click by submitting a migration modification (described above). In the main study workspace:

From the sidebar (My Current Actions), choose Assign PI Proxy.

On the Assign PI Proxy pop-up, check the box next to the name of the intended proxy.

Click OK.
Q: Can study team member roles be changed throughout the course of a study?

A: Yes. The Primary Contact and/or PI Proxy can be re-assigned at any time. Other changes (e.g. changing the PI to another study team member or adding study team members) would require a study modification, just like in iRIS.

Q: Can PI Proxies be added before they are approved as study team members?

A: A PI Proxy can be assigned at any time in the life of the study, even in Pre-Submission. The Proxy does have to be in the system as a study team member.

Q: If the PI/PI Proxy is submitting items, will he or she receive a system notification?

A: When a study is submitted, all study team members can view the submission activity, but there are no automatic notifications associated with submitting an item. You can see that an item has been received by the IRB by noting that the study status has changed from “Pre-Submission” to “Pre-Review”.

Q: Can you search in the system for all studies assigned to one PI?

A: Yes. Click IRB offers the ability to search transactions by a variety of search terms. Use the “All Submissions” tab and you can search by the last name of the PI to find all of his/her studies.

Q: Can you modify all studies assigned to one PI at the same time, e.g., add a CRA to all of Dr. Smith’s studies with one request?

A: No, Click IRB does not allow modifications to apply to more than one study. Each study must be modified individually.

Q: How do I submit adverse event information?

A: To report an adverse event (unanticipated problem), protocol deviation, non-compliance, confidentiality breach or other new information, select ‘Report New Information’. The form identifies the types of information you must report and allows you to attach supporting documentation.

EDITING STUDY INFORMATION AND RESPONDING TO CLARIFICATION REQUESTS

Q: If the IRB has requested clarification, who will receive the email notification?

A: The PI, the PI Proxy and the Primary Contact.

Q: How can I respond to a request for clarifications?

A: After providing the requested information, you will need to add a comment (‘Add Comment’) confirming that this has been done. The PI/Proxy will receive an email alerting them to the comment and containing a link that will take the PI directly to the study workspace, where they will submit the response (see below).
The PI/Proxy will need to be trained that any time a comment is submitted for one of their studies, they will receive this email and should click on the link provided to determine if their sign-off may be required.

Q: How do I revise documents in Click and where do I upload them?

A: If you need to modify study documents prior to IRB approval:

1. From My Inbox, click the name of the study to open it.

2. Click the Documents tab.

3. Click the document in the Draft column and save it to your computer.

4. Open the document.

5. Enable the Track Changes feature and update the document.

6. When finished, **replace the original study document with the tracked-changes version.** When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.
To change documents for an approved study (requires submission of a modification):

1. Click **IRB** in the top left navigation area and select the **Active** tab.

Click the name of the approved study.

Click the **Documents** tab.

Click the document in the **Final** column and save it to your computer.

**Tip:** In some cases, you may only be able to use the draft document because the final document is a PDF. In this case, the draft document may contain tracked changes and comments. To make its content match the final PDF, use the review features in Word to accept all the changes and remove any comments. Use this clean document as a starting point for your revisions.

Open the document and revise it in tracked-changes format.

When finished, replace the original document with the tracked-changes version in the modification. When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.

**Q:** Is there a limit on the size of attached documents in Click?

**A:** No, but use of wireless connectivity is not recommended for work involving file transfers, as this may slow down your experience in Click.
Q: Can I discard or withdraw a submission?

A: You can **discard** a submission ONLY while it is in Pre-Submission. The ‘discard’ activity will be available on the left hand side of the screen under “My Current Actions”. If the PI or PI Proxy does not see the ‘discard’ option, this means the transaction cannot be withdrawn.

You can **withdraw** a submission until the IRB has taken action (i.e. completed its review) on the submission. The withdraw activity will be available on the left hand side of the screen under “My Current Actions”.

**Please contact the IRB before withdrawing a submission**. If an item is past Pre-Submission, the IRO has already begun a pre-review and if you withdraw anything, the assigned IRB coordinator will need to know.

Q. How do I close a study?

A. You need to select ‘Create Modification/CR’. You’ll then see a screen that says ‘Modification/Continuing Review/Study Closure’. Select ‘continuing review’ and continue.

On the next page, answer the enrollment question and then note question 2 – **Research Milestones**. If you check the first four milestone boxes, you’ll see a pop-up that says “I acknowledge that this study will be closed”. Check that box and complete the rest of the form (see below).

**Continuing Review / Study Closure Information**

1. **Specify enrollment totals:**

<table>
<thead>
<tr>
<th>Subjects Enrolled</th>
<th>Total</th>
<th>Since Last Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>At this investigator’s sites:</td>
<td>☑️</td>
<td></td>
</tr>
<tr>
<td>Study-wide:</td>
<td>☑️</td>
<td></td>
</tr>
</tbody>
</table>

2. **Research milestones**: (Select all that apply. If study status is actively enrolling, do not check any of the boxes below.)

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects

3. **Important!** If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.
When it bumps you back to the study workspace, select ‘Submit’.

**My Current Actions**

- [Submit](#)
- [Discard](#)
- [Manage Ancillary Reviews](#)
- [Add Comment](#)
- [Notify PI of Submission Ready for Review](#)

**Q:** Do individuals assigned on the “Guest List” have any additional permission beyond viewing? Can they open and/or download attachments?

**A:** Individuals on the guest list can add a comment, but cannot access reviewer comments. Guests can view all other aspects of the study, including opening and downloading attachments, but cannot edit.

**Q:** Why have I not heard back from the IRB about my submission?

**A:** Open the submission workspace and check the submission status. This can be seen in either the blue status box in the upper left corner or in the “States Overview” flowchart for the submission.

If the study status is “Pre-Submission”, then the submission hasn’t actually been submitted yet and requires sign-off by the PI/Proxy in order to get the transaction to the IRB. If someone other than the PI created the submission, they will
need to notify the PI that the item is ready for sign-off (see below). Otherwise the item will not appear in the PI’s inbox as a task to complete.

Q: Will I still receive annual re-approval reminders?

A: Yes. In Click IRB, there are system notifications 30, 60 and 90 days prior to expiration but a “due date” is not called out. To be assured that the IRB will have appropriate time to review your continuing review, you will need to submit your continuing review in Click according to the due dates indicated in the Swedish IRB Meeting Schedule.

For full Board review, the deadline is approximately 60 days prior to expiration.

For expedited (minimal risk) study review, the deadline is approximately 30 days prior to expiration.

The expiration date in Click is the “Approval End” date in the upper left-hand corner of the study workspace.

The table below summarizes how to get started submitting each type of information to the IRB.
<table>
<thead>
<tr>
<th>To submit this type of information...</th>
<th>...start here...</th>
<th>...and click this button</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuing review</td>
<td>From the Active tab, click the study name</td>
<td><img src="#" alt="Create Modification / CR" /></td>
<td>You can submit a continuing review and a modification at the same time. The first form prompts you to identify the type of information to submit.</td>
</tr>
<tr>
<td>Modifications to an active study</td>
<td>From the Active tab, click the study name</td>
<td><img src="#" alt="Report New Information" /></td>
<td>To request study closure, submit a CR. Based on the research milestones completed, the study may be closed.</td>
</tr>
<tr>
<td>Study Closure</td>
<td>From the Active tab, click the study name</td>
<td><img src="#" alt="Report New Information" /></td>
<td>Report new information as soon as you become aware of it. The form identifies the types of information you must report.</td>
</tr>
<tr>
<td>New information or an adverse event report</td>
<td>For new information about a particular study, start from the Active tab and click the study name</td>
<td><img src="#" alt="Report New Information" /></td>
<td>Report new information as soon as you become aware of it. The form identifies the types of information you must report.</td>
</tr>
<tr>
<td></td>
<td>For information affecting multiple studies, start in My Inbox</td>
<td><img src="#" alt="Report New Information" /></td>
<td>Report new information as soon as you become aware of it. The form identifies the types of information you must report.</td>
</tr>
<tr>
<td>New study for review</td>
<td>My Inbox</td>
<td><img src="#" alt="Create New Study" /></td>
<td>See Study Submission Guide, Creating a New Study.</td>
</tr>
<tr>
<td>Updates to a new study that hasn't been submitted for IRB review yet</td>
<td>Within the study</td>
<td><img src="#" alt="Edit Study" /></td>
<td>See Study Submission Guide, Editing a Study.</td>
</tr>
</tbody>
</table>