

# Click IRB Resources

## Frequently Asked Questions

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

A: To log in to Click IRB, go to Citrix to open the list of viewable applications. Select the Click application icon. You will be presented with a Click session login screen. Log in with your Children's username and password and choose to view the IRB module. For detailed instructions, see the Quick Guide [Logging In](#).

**Q: Can you add a direct hyperlink to Click IRB from IRB webpage?**

A: No, because this application is accessed via Citrix, we are unable to provide a direct hyperlink to Click from the IRB webpage.

**Q: What if a study team member does not have Seattle Children's login or is not in Lawson? How can they obtain access to Click?**

A: Anyone with a Seattle Children's Lawson record should have access to Click and be able to log in. If you do not have a Lawson record and need to obtain one, you can obtain one via the Seattle Children's "NEAT" process. Details for NEAT onboarding can be found on CHILD (accessible via the Children's Intranet). This information is only accessible via the Seattle Children's intranet. If you do not currently have access to CHILD, you will need to speak with someone on your study team who does have access to get started.

**Q: If someone on the study team is not in Lawson and does not to access the study in Click, how do I add them 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: Do I need to get training?**

A: Training is very strongly recommended before you begin. While Click IRB is an intuitive system, it is accompanied by changes in business process and shifts in responsibility. Your study team will be more successful if you have a clear understanding of Click IRB. Visit the [Click IRB Resources](#) page for more information or check the Learning Center.

**Q: Can I keep using the legacy IRB system?**

A: Existing legacy IRB forms and processes will no longer be accepted after the required use date of **March 1, 2016**. If you are in another exceptional circumstance that means you cannot use Click IRB, then please contact the [IRB](#).

**Q: Why am I getting messages from Click?**

A: PIs, PI Proxies, and Primary Contacts will receive email notifications related to these activities and deadlines:

- 90, 60, and 30 days before study approval end date
- When a study has lapsed
- Requests for clarification or modifications required to secure approval for any transaction
- New comments were logged in the system
- Determination letters sent by the IRB Analysts

# Click IRB Resources

## Frequently Asked Questions

**Q: Is my study number changing? What does PIRO mean?**

A: Existing IRB study numbers are folded into the new Click Number as PIROSTUDYXXXXX. PIRO is the name of the legacy IRB database. XXXXX would be your existing study number from the legacy system.

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

A: Anyone with a record in Lawson can access Click IRB, but to view specific study documents, they must be a part of the study team in Click IRB. For studies imported into Click IRB from the legacy IRB system, only the PI and the Primary Contact will have access to the study unless a modification request is submitted to add the individual. For details, view the Quick Guide [Studies Migrated from the Legacy System](#)

**Q: Why can't my current study team see my imported legacy study in Click IRB?**

A: For imported studies brought into Click IRB, only the PI, PI Proxy (if applicable), and the Primary contact will have initial access to the study. The reason for this was mainly due to technical concerns with the data that we were able to import from our legacy database. If you have a legacy study that was imported to Click, you will need to add the current study team as a study "modification" in order to get them access to the study in Click IRB. For details, view the Quick Guide [Studies Migrated from the Legacy System](#).

**Q: How does the study team access and review study documents before submitting?**

A: Anyone who is part of the study team can review the study and its associated documents before it is submitted. For more detailed information about what changes have been made and who on the study team made them, you can view the study history in Click.

**Q: As a PI, how do I designate a "PI Proxy" to take action on my behalf?**

A: Assigning a PI Proxy in Click IRB delegates your authority to one or more alternate people who can then submit new studies and updates to existing studies in Click IRB on your behalf. For detailed instructions, see the Quick Guide [PI Proxy](#).

**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 non-study team member) would require a study modification—just like in the legacy IRB system. For more information, view the Quick Guide [Study Roles in Click](#).

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

A: It depends. A PI Proxy can be assigned for initial studies anytime, even during Pre-Submission. After the study is approved, the team member has to be currently approved on the study to be assigned as a Proxy.

**Q: Can both the PI and PI Proxy submit at the same time?**

A: If two people are in the system making changes at the same time, once the first person submits the study, the submit button will not be available to the other person. If by chance both people click the Submit button at the exact same moment, one person will be successful and the other will receive an error message. The key to avoiding this situation is clear communication between the PI and Proxy and to designate one person to submit your study.

# Click IRB Resources

## Frequently Asked Questions

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

A: One of the advantages of Click is that anyone who is part of a study can see all activities conducted on that study. 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 dark blue bubble says “Pre-Review”. Please see the Quick Guide [States vs. Activities](#) and the Quick Guide [Correspondence within Click](#) for more information.

**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 one at a time.

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

A: PI, the PI Proxy (if applicable), and the Primary Contact. For details, view the Quick Guide [Correspondence within Click](#).

**Q: What does the Click “My Inbox” mean?**

A: The Click system is intended for multiple types of business, including COI. The “My Inbox” allows for a view into all of Click business. When you log in to Click, you will be in “My Inbox” so you will see all COI and IRB and any other Click business. If you only want to see IRB business, simply click on the “IRB” tab in the upper left-hand corner.

**Q: Where are the HIPAA forms in the Click IRB library?**

A: Required elements of HIPAA have been incorporated into the consent/parental permission templates found in the Click IRB Library. This means that you will not have a separate HIPAA form for these studies. For studies transitioned to Click from the legacy IRB system, you will upload your current HIPAA forms into the Click system during a study renewal or modification on the “Supporting Documents” tab.

**Q: The new combined consent/HIPAA form in the Click library is great! Can I combine my legacy IRB consent and HIPAA forms using the new template?**

A: This is not advisable for many reasons, most importantly because the new templates are designed to work with the entire Click IRB library with all the new roles and responsibilities transition to Click IRB. Transfers onto the new template will generally only be allowed for legacy IRB studies under very special circumstances. If you have concerns or questions about this, please contact the [IRB](#).

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

A: To add an organization to the funding list in Click IRB, contact [NewClickOrgRequest@seattlechildrens.org](mailto:NewClickOrgRequest@seattlechildrens.org). You can expect a response in one full business day.

# Click IRB Resources

## Frequently Asked Questions

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

A: Before submitting an external IRB study, see the [External IRB Process](#) page on the IRB Website and use the [External IRB Studies](#) Quick Guide. To add a new external IRB to the list in Click IRB, contact [NewClickOrgRequest@seattlechildrens.org](mailto:NewClickOrgRequest@seattlechildrens.org). You can expect a response in one full business day.

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

A: No, but use of wireless connectivity is not recommended for work involving file transfers as this may slow down your experience in Click IRB.

**Q: When preparing to submit an initial study, if you click back or exit and did not hit save, will you lose edits?**

A: You'll get a prompt that prevents the Click system from losing your edits.

**Q: Can I withdraw a transaction?**

A: For the most part the answer is “yes” until the IRB has taken action (i.e. completed its review) of the transaction. The simple way to know this is have the PI or PI Proxy log into Click IRB and find the transaction. If there is the ability to withdraw it, a “withdraw” 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 withdraw button, that means the transaction cannot be withdrawn. If you have questions, please contact the [IRB](#).

**Q: Will individuals who are 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 they cannot change the SmartForms or attachments.

**Q: In an application for a new study where the only study site is SCH, should a co-investigator who is based at UW be listed as an “external team member” or not?**

A: The UW members should be listed as internal members if they need access to Click (to get consent forms, etc). They can be added if they are already in the drop down list or they can use the NEAT onboarding process available on CHILD through Research HR to get on the internal list. If they do not need access to Click, you can list them as External team members without having to go through the NEAT process.

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

A: Check the “States Overview” for the transaction. Is it saying the transaction is in “Pre-Submission”? If yes, then your transaction is still with you and the IRB does not have it yet. See the Quick Guide [States vs. Activities](#) for more information about how to track your transaction’s progress thru the IRB process. In order to get the transaction to the IRB, a PI or PI Proxy needs to submit it using the “submit” activity. Click also offers visibility about who is assigned to the transaction and about where in the workflow your item currently resides.

**Q: Why don't I have a submit button?**

A: Only the PI or PI Proxy will have the submit button under “My Current Actions”. Your view is tailored to your role in the Click system as well as your role on the study team.

# Click IRB Resources

## Frequently Asked Questions

### **Q: Will WIRB studies use the new consent forms? Separate HIPAA?**

A: For NCI CIRB or WIRB studies, attach the relevant documentation per current business practices as a supporting document to the External IRB SmartForm. For more details, see the Quick Guide [External IRB Studies](#) and [External IRB Process](#) page on the IRB Website. A revised CIRB and WIRB consent form with the embedded HIPAA language will be available in the future. For now, you can use the standard CIRB or WIRB consent form and attach a separate HIPAA form when you submit these studies.

### **Q: Why is Click IRB so concerned about the COI status of study team members?**

A: The new Click IRB system is linked with Click COI. Transactions can be held up if any member of the study team has a incomplete disclosures in Click COI. It is important for study teams to have all team members have their disclosures up to date. You can review the COI status of your team members in Click IRB by clicking on the Project Contacts tab. The “Disclosure Review Status” help text has a chart to help you understand what the various statuses mean. If any members have an incomplete status, they will need to log-in to Click to complete their disclosures.

### **Q: I am having problems understanding where to attach documents in Click. Help!**

A: Follow the Quick Guide [Attaching New and Revised Documents](#) for best practices for attaching documents. Common Problems for attaching documents in Click include:

1. Attaching documents to the wrong SmartForm page
2. Trying to attach document by putting it in a comment rather than in the Smart Forms
3. Up-loading new documents rather than using “Upload Revisions” to replace an existing document

### **Q: What is happening to the legacy IRB Forms?**

A: The legacy IRB forms have been retired. Click uses SmartForms and protocol attachments to capture the information that was once collected by the legacy IRB application forms. You will not be attaching legacy IRB forms to the Click system unless your study has been migrated and you are making changes to legacy documents..

### **Q: What is different about the Click IRB Renewal Reminders?**

A: In the legacy IRB system, you were sent a single reminder approximately 10 to 12 weeks prior to study expiration with a “due date” for the continuing review materials. In Click IRB, there are system notifications 30, 60 and 90 days prior to expiration and a “due date” is not called out. In general 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 at least 45 days prior to expiration. You can see your expiration date by navigating to the “parent” study record in Click and noting the “Approval End” date in the upper left-hand corner of the page.