Click IRB for PIs and Study Teams
Deep Dive Training Workbook

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10/27/15
Presented by: Human Subjects Protection Program
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>TABLE OF CONTENTS</td>
<td>2</td>
</tr>
<tr>
<td>WELCOME</td>
<td>3</td>
</tr>
<tr>
<td>OVERVIEW OF TRAINING MODULES</td>
<td>4</td>
</tr>
<tr>
<td>OVERVIEW OF THREE KEY CONCEPTS</td>
<td>6</td>
</tr>
<tr>
<td>UNDERSTANDING SUBMISSION TYPES</td>
<td>9</td>
</tr>
<tr>
<td>SELECTING AND COMPLETING A PROTOCOL TEMPLATE</td>
<td>10</td>
</tr>
<tr>
<td>SELECTING AND COMPLETING OTHER FORMS</td>
<td>14</td>
</tr>
<tr>
<td>CREATING A NEW STUDY</td>
<td>18</td>
</tr>
<tr>
<td>ASSIGNING STUDY TEAM MEMBERS, PRIMARY CONTACT AND PI PROXY</td>
<td>24</td>
</tr>
<tr>
<td>IDENTIFYING A FUNDING SOURCE</td>
<td>26</td>
</tr>
<tr>
<td>EDITING A DRAFT STUDY</td>
<td>28</td>
</tr>
<tr>
<td>SUBMITTING A NEW STUDY FOR REVIEW</td>
<td>31</td>
</tr>
<tr>
<td>SUBMITTING EXTERNAL IRB STUDIES</td>
<td>35</td>
</tr>
<tr>
<td>WITHDRAWING A SUBMISSION</td>
<td>36</td>
</tr>
<tr>
<td>DISCARDING A SUBMISSION</td>
<td>38</td>
</tr>
<tr>
<td>VIEWING DISCLOSURE STATUS</td>
<td>39</td>
</tr>
<tr>
<td>MANAGING A GUEST LIST</td>
<td>41</td>
</tr>
<tr>
<td>FINAL BUSINESS GUIDANCE</td>
<td>43</td>
</tr>
<tr>
<td>GLOSSARY OF CLICK IRB TERMS</td>
<td>44</td>
</tr>
</tbody>
</table>
Welcome

Welcome to Click IRB training. Our goal is to provide you with the tools and knowledge you need to navigate and use Click IRB as an integral part of working with SCRI's IRB.

What Is Click IRB?

Click IRB is a module in the Click suite of software tools to support research. The Click IRB software is the result of years of analysis and development by experts in the field of human subjects research.

How and Why Does Click IRB Help?

The system will bring a number of advantages to the federally-mandated management of human subjects research at Seattle Children’s. The most notable gains include increased efficiency and greater standardization across documents and processes used by the Institutional Review Board (IRB), and increased visibility during the review process.

How Will Click IRB Impact Your Job?

Following the initial deployment of Click IRB on September 28, 2015, all new studies as well as activities for existing studies may be submitted and reviewed using Click IRB (optional use period). After the final transition to the new system on January 4, 2016, all IRB work will be conducted using Click IRB (required use).

Click IRB brings changes to the way submissions are made and reviews are managed. These changes include:

• Protocols are required for new study submissions. Please note that if a protocol already exists for a study, that can be attached along with site-specific information to meet this requirement.
• An Investigator Manual is being introduced that should be a helpful resource to researchers as a statement of their responsibilities.
• Terminology changes that more closely reflect regulatory language/concepts.

What Do We Need From You?

As you all are aware of the constant need for innovation and process improvement, we are calling on your spirit of collaboration during the transition to the new system. Watch iKnow for announcements, and participate in the orientation sessions and hands-on workshops that are available to the research community.

How Will We Support the Change?

The Human Subjects Protection Program team is offering a robust training program to support the transition to Click IRB. Hands-on workshops and self-serve resources will be available throughout the transition period, starting in October 2015.
Overview of Training Modules

The training modules begin with an **Essentials** workshop which offers a foundational understanding of the Click IRB system, and then move into the two optional **Deep Dive** workshops which provide more detail on each of the “states” or stages that a study moves through on its way to approval and completion, and hands-on practice with Click.

**Notes:**

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<table>
<thead>
<tr>
<th>Deep Dive Learning Objectives</th>
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</thead>
<tbody>
<tr>
<td><strong>Deep Dive 1</strong></td>
</tr>
<tr>
<td>Select the correct Protocol Template for a new study submission</td>
</tr>
<tr>
<td>Respond to requested clarifications in review (Research community)</td>
</tr>
<tr>
<td>Respond to required modifications in review</td>
</tr>
<tr>
<td>Respond to determinations (Research community)</td>
</tr>
<tr>
<td>Track the progress of a submission (Research community)</td>
</tr>
<tr>
<td><strong>Deep Dive 2</strong></td>
</tr>
<tr>
<td>Initiate modifications, new information and continuing reviews/closure for a study (Research Community)</td>
</tr>
<tr>
<td>Prepare and submit via Click the four core system transactions (New Studies, Continuing Reviews, Modifications and Reportable New Information) for review by SCRI’s IRB, using reliable methods</td>
</tr>
<tr>
<td>Understand how to handle migrated studies</td>
</tr>
</tbody>
</table>
Overview of Three Key Concepts

Key Concept #1: Roles in Click vs. Study Roles

The Primary Investigator (PI) role for a study comes with certain authorities tied to regulatory oversight: submitting a new study, and submitting follow on submissions to the IRB.

There is a PI Proxy role designed to extend the PI’s role in Click to another study team member, either on a short-term basis or for the life of the study.

There is also a Primary Contact role, which by default is the person who initially sets up the study. The Primary Contact, who might be the PI, the PI Proxy, or another study team member, will receive email notifications generated by the system.

For more detailed information about the different roles in a study and how they are managed, review the Quick Guide – Understanding Study Roles in Click.

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Key Concept #2: It’s In the Click IRB Library

The IRB Library contains all templates, Standard Operating Procedures, Manuals and Flowcharts, worksheets, and training materials. It is the single source of truth for this information and is maintained and updated by the Human Subjects Protection Program team. The templates in the library will always be the most current version, and the IRB staff recommends that you start here when creating a new study, rather than editing a document from a previous study.

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Key Concept #3: Attachments to SmartForms

At times you will be working outside the system to prepare documents that you will then upload to Click when prompted on a SmartForm. These are typically Word documents. Uploaded attachments are stored in Click; as the document is replaced with newer versions, Click will track the change history.

For example, when submitting a new study you’ll be asked to attach a protocol document. You’ll prepare this document outside of the Click environment and attach it when prompted.

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Understanding Submission Types

A new study is one of the four main forms of submissions in Click IRB. At certain points in the life of a study the other three forms of submissions (continuing review, modification, or RNI (reportable new information) ) may be necessary. The process for follow-on submissions in Click IRB will be similar to that of a new study, involving use of the IRB workspace, the study workspace, and SmartForms.

Reliable Methods for Submission Types

- Modifications are not permitted prior to the study being approved.
- In Click IRB, only one of each type of modification can be open on a study at a time.

Notes / Other Reliable Methods:

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Selecting and Completing a Protocol Template

Overview

It is recommended to prepare all relevant documents (attachments) prior to completing the SmartForms in the Click IRB electronic system. The protocol is of primary importance. This section provides an overview on selecting and completing a protocol template, and detailed guidance following the overview.

Selecting a Protocol Template

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Select the template to fit your needs: There are several protocol templates available in the Library that you can choose from. It is important to choose the one that fits the study you are conducting.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If you cannot determine which protocol template is the correct one, stop and schedule a consult with the IRB. This can help get your project on the right track and save you valuable time.</td>
</tr>
</tbody>
</table>

Completing a Protocol Template

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Choose the correct <strong>Protocol Template</strong> for your study. As stated above, there are several templates available in the Library that you can choose from. It is important to choose the one that fits the study you are conducting.</th>
</tr>
</thead>
</table>
| Step 2 | Use the **Protocol Template** Correctly. Once you have selected the correct template, here are some tips to help you be successful:  
  • Read and follow the provided instructions.  
  • Pay attention to the embedded hints in the templates.  
  • Do not delete sections of the document. If it does not apply, type “Not applicable” or use some way to indicate that this does not apply to your study.  
  • Know how to use the referenced Click Checklists in the templates. If the instructions tells you that you must address certain information found in a Checklist document, you will need to include it in the protocol that you submit to the IRB. Click Checklists summarize the information that is necessary for the research to comply with regulations (e.g. OHRP, FDA, GCP). If you do not provide the necessary information, your study might get deferred or delayed.  
  If you do not understand what the template is asking for or how to use the necessary Click Checklists, it is best to schedule a consult and get advice from the Human Subjects Protection Program (HSPP) staff. You can reach the staff at irb@seattlechildrens.org or 206-987-7804. |
|        | Save your protocol with a new file name, available to attach with your submission. |
Reliable Methods for Selecting and Completing a Protocol Template

• Incorporate the use of checklists found in the IRB Library and on the IRB Website into your preparation of the protocol template.
• Turn off “Track Changes” for your protocol template submission.
• Use a “dummy” or placeholder document as the attachment if your protocol is in draft at the time you create the submission. Just make sure you replace it with the final version before you submit.
• In cases when have a template sent to you by the sponsor/coordinating center: If you’ve already got a protocol you can attach it, and you’re just doing a site supplement.
• See the Guidance section below for additional key points to remember when developing an Investigator Protocol.
• See the Reliable Methods for Selecting and Completing Other Forms in the next section of this workbook for general tips on attaching documents with your submission.

Notes / Other Reliable Methods:

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**Guidance: Selecting and Completing a Protocol Template**

Use the “TEMPLATE PROTOCOL(S)” provided as a starting point for drafting a new Investigator Protocol, and reference the instructions and hints provided for the information the IRB looks for when reviewing research. There are multiple types of Protocol Templates available so you can choose the one that best fits your project (please refer to the Protocol Tip Sheets in the IRB Library for more information).

<table>
<thead>
<tr>
<th>Protocol Template Name</th>
<th>When should I use this template?</th>
<th>What former IRB application does this best correspond to?</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-503 – Protocol</td>
<td>Most research studies that do not already have a protocol available from the Sponsor</td>
<td>IRB-ITHS New Application</td>
</tr>
</tbody>
</table>
| HRP-503A – Protocol – Expedited No Direct Contact Study | Research involving materials (data, documents, records, or specimens) that have been collected for non-research purposes where you will not have direct contact with participants and will likely qualify for waivers of consent and HIPAA. See HRP-313 – Worksheet – Expedited Review for more information  
**Note:** this template is never appropriate for an FDA regulated study. This template can sometimes apply to the use of existing materials that were collected for research purposes. Please seek a consult if you want guidance for your particular study. | IRB Expedited Review Application                                                                                                                                                                                                     |
| HRP-503B – Protocol – Exempt                    | Studies that fit one of the exempt categories of review (see HRP-312 – Worksheet – Exemption Determination)  
**Note:** This template is never appropriate for an FDA regulated study                                                                                          | Application for Exempt Determination or Other Status Not Requiring IRB Approval                                                               |
| HRP-503C – Protocol Other Status Determination  | Projects that you are seeking a determination of not research, not human subjects research, not engaged (e.g. case reports, QI/QA research)  
**Note:** This template is never appropriate for an FDA regulated study                                                                           | Application for Exempt Determination or Other Status Not Requiring IRB Approval                                                               |
| HRP-508 – Site Supplement to Sponsor Protocol   | Research studies where the Sponsor has provided a protocol document for conduct of the study                                                                                                                                                | IRB-ITHS New Application                                                                                                                     |
Key points to remember when developing an Investigator Protocol:

• The italicized bullet points in the “TEMPLATE PROTOCOL(S)” and the hints provided in green highlighted font serve as guidance to investigators when developing an Investigator Protocol for submission to the IRB. All italicized and green highlighted comments are meant to be deleted prior to submission.

• For any items described in the sponsor’s protocol or other documents submitted with the application, investigators may simply reference the page numbers of these documents within the Investigator Protocol rather than repeat information.

• When writing an Investigator Protocol, always keep an electronic copy. You will need to modify this copy when making changes to the Investigator Protocol.

• If you believe your activity may not be Human Research, contact the HSPP Office prior to developing your Investigator Protocol.

• Note that, depending on the nature of your research, certain sections of the template may not be applicable to your Investigator Protocol. Indicate this as appropriate.

• You may not involve any individuals who are members of the following populations as subjects in your research unless you indicate this in your inclusion criteria because the inclusion of subjects in these populations has regulatory implications.
  o Individuals who are not yet adults (infants, children, teenagers)
  o Adults unable to provide legally effective consent
  o Pregnant women
  o Prisoners

• If you are conducting community-based participatory research, you may contact the IRB/HSPP Office for information about:
  o Research studies using a community-based participatory research design
  o Use of community advisory boards
  o Use of participant advocates
  o Partnerships with community-based organizations

• All IRB checklists and worksheets can be found on the IRB Library in Click. These checklists are used by the IRB for initial review, continuing review, and review of modifications to previously approved Human Research; the content is based upon the regulations. You are encouraged to use the checklists to write your Investigator Protocol in a way that addresses the criteria for approval.

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Selecting and Completing Other Forms

Overview

It is a best practice to create relevant documents in order to be prepared with attachments prior to completing the SmartForms in Click IRB. Examples of key documents you will want to have prepared in addition to the protocol include:

- Consent Forms
- Recruitment Materials
- Support Materials

Completing a Consent Template

<table>
<thead>
<tr>
<th>Choose the correct Consent/Assent Template for your study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are several templates available in the Library that you can choose from. It is important to choose the one that fits the study population you are targeting. If you cannot determine which consent template is the correct one, stop and schedule a consult with the IRB. This can help get your project on the right track and save you valuable time.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use the Consent/Assent Template correctly.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once you have selected the correct template, here are some tips to help you be successful:</td>
</tr>
<tr>
<td>• Read and follow the provided instructions. Pay special attention to instructions involving HIPAA language in the templates if your studies involves PHI.</td>
</tr>
<tr>
<td>• Pay attention to the embedded hints in the templates.</td>
</tr>
<tr>
<td>• In general, do not delete sections of the templates. These templates are designed to be compliant with the requirements as outlined in HRP-314A – Worksheet – WORKSHEET ADDENDUM-Consent Form Requirements.</td>
</tr>
<tr>
<td>If you do not understand how to use the provided templates or which one to choose, it is best to schedule a consult and get advice from the Human Subjects Protection Program (HSPP) staff. You can reach the staff at <a href="mailto:irb@seattlechildrens.org">irb@seattlechildrens.org</a> or 206-987-7804. This step can save you time!</td>
</tr>
</tbody>
</table>

Selecting and Completing Recruitment Documents

<table>
<thead>
<tr>
<th>Use the “TEMPLATE RECRUITMENT FLYER” or “TEMPLATE RECRUITMENT LETTER” to create recruitment materials.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review the IRB’s “WORKSHEET: Advertisements (HRP-315),” to ensure that all elements are addressed.</td>
</tr>
</tbody>
</table>

Note: All recruitment materials must contain all of the required and all additional appropriate elements of recruitment.
Reliable Methods for Selecting and Completing Other Forms

- Check the IRB Library to ensure that you are using the most recent version approved by the IRB.
- Ensure your documents are not password-protected and can be re-opened.
- Ensure you attach the documents to the appropriate page in Click IRB to avoid your re-work. This is tied to the Finalization and Watermarking functions of Click IRB.
- Click IRB calls for you to provide a name and version for any document you attach. Ensure you provide a name and version that makes sense and matches the name and version noted within the document itself.
- Links to Recruitment Materials Templates are available in the IRB Library.
- We recommend that you indicate the version of your recruitment materials in the file name as you make revisions. It is important to ensure that the version information you use within the document matches the information you provide in the electronic system for the document.
- Use of the published Consent Form Templates are required. Please contact the IRB if you have a compelling reason why that is not possible.

Notes / Other Reliable Methods:

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**Guidance: Selecting and Completing Consent Documents**

Use the “TEMPLATE CONSENT DOCUMENTS” to create a consent document. In addition to those available within the Click IRB electronic system, lesser used Template Consent Documents may be available on the IRB Web site.

Note that all long form consent documents and all summaries for short form consent documents must contain all of the required and all additional appropriate elements of informed consent disclosure. Review the “Long Form of Consent Documentation” section in the IRB’s “WORKSHEET: Criteria for Approval (HRP-314),” to ensure that these elements are addressed. When using the short form of consent documentation, the appropriate signature block from “TEMPLATE CONSENT DOCUMENT (HRP-502)” should be used on the short form. See HRP-090 and HRP-091 as well as the Appendices to this document for further information.

It is required that you indicate the versions of your consent documents as you make revisions to ensure that you use the most recent version approved by the IRB. It is important to ensure that the version information you use within the document matches the information you provide in the electronic system for the document.

The following are the consent templates you can choose from:

<table>
<thead>
<tr>
<th>Protocol Template Name</th>
<th>When should I use this template?</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-502 – Template – Consent Document</td>
<td>Studies enrolling participants who are all over 18 years of age.</td>
</tr>
<tr>
<td>HRP-502A – Consent Assent Parental Permission Template</td>
<td>Studies including participants who are minors who will provide assent (13-17) and adult participants. This forms serves 3 purposes: Parents give permission for any minors to participate; Adult participants give their consent; Minors ages 13-17 give their assent</td>
</tr>
<tr>
<td>HRP-502B – Parent Participant Addendum</td>
<td>Studies where parents are also human subjects</td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> This template is generally limited to activities like collecting medical history; questionnaires/surveys; blood/urine collection. DNA testing is not eligible.</td>
</tr>
<tr>
<td>HRP-502C – Parental Permission ONLY Template</td>
<td>Studies where parents are giving permission for minor participants who are not providing written assent or the minors are providing assent on the Assent form (HRP-502G; generally when all the children are under 13 years of age)</td>
</tr>
</tbody>
</table>
### HRP-502D – Information Sheet Template

Studies where you are requesting a waiver of documentation of consent for survey/questionnaire studies (see information in HRP-411 – CHECKLIST – Waiver of Written Documentation of Consent). This means you are not required to get a signature on a consent form.

**Note:** If you are thinking of requesting a waiver of documentation of consent for a study involving more than surveys/questionnaires, please request an IRB consult to guide you in choosing a template to use. This template can be adapted for on-line use.

### HRP-502E – Exempt Consent Form Template

Consent for Exempt studies (see HRP-312 – WORKSHEET – Exemption for more information)

### HRP-502F – Language Resource Text

All studies. This document is resource for consent form wording for studies.

### HRP-502G – Assent Form Template

Studies where written assent will be obtained from children 7-12 years of age.

### HRP-506 – Emergency Use Consent Template


### HRP-507 – Template – Consent Document – Short Form

Studies approved to use the short form consent process. See HRP-090 – SOP – Informed Consent Process for Research and HRP-091 – Written Documentation of Consent

### HRP-508 – Template – Short Form Assent English

Studies approved to use the short form assent form

### Notes:
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Creating a New Study

Overview

The simplest approach to creating a new study for review is to follow the SmartForms in order, answering the questions and clicking **Continue** to save your information and move to the next form. Upon completion of the forms, click the **Finish** button. Let’s take a closer look.

**Note:** Before you begin, be sure you have gathered files and information about your study such as:

- Specific Protocol document for your study
- Supporting information files
- Financial interest status for each of your study team members
- Contact information and IRB oversight information for external sites involved in the study.

1. Click the **My Inbox** link in the upper right corner. From the sidebar; expand **IRB**. Click **Create New Study**.

2. Complete the **Basic Information** page and click **Continue**.

   **HINT:** click the **Library** link to review protocol templates.

!! When you create a study, your name is defaulted as the Principal Investigator. If you are completing the study on behalf of the PI be sure to select the correct PI.
If applicable, complete the Funding Source page by clicking Add.

On the Add Funding Source pop up, use the Select button to choose a funding source from the list, then click OK.

Click Continue to advance to the next page.

Complete the Study Team Members page by using the Add button to add study team members.
If you are completing the study on behalf of the PI be sure to add yourself as a study team member.

The Disclosure Review Status column shows the financial disclosure status on existing (active) disclosures.

Important detail about question #2! Do not attach information about team members you were able to select in question #1. Most study team members (even those that are students) have a Seattle Children’s profile and therefore should be included in the list in question #1. If you are unsure how to proceed, contact your IRB staff for assistance.

Complete the Study Scope page and click Continue.

Based on your answers to these questions you may be required to complete additional pages. Specifically, if you answer:

Yes to question #1 you will be prompted to complete the External Sites page.
Yes to question #2 you will be prompted to complete the Drugs page.
Yes to question #3 you will be prompted to complete the Devices page.
Step 5.1 If the **External Sites** page appears, click **Add** to complete. When finished click **Continue**.

Step 5.2 If the **Drugs** page appears, click **Add** to complete. When finished click **Continue**.

Step 5.3 If the **Devices** page appears, click **Add** to complete. When finished click **Continue**.
Step 6
Attach Consent Forms and Recruitment Materials by clicking the Add button in each category. When finished click Continue.

Step 7
Attach any Supporting Documents by clicking the Add button to include documentation that you did not attach on previous pages. When finished click Continue.

Step 8
On the Final Page, click Save and Close.

⚠️ If you need to go back to another page in the smart form, use the Jump To menu located in the menu bar.

If you are the PI and you are ready to Submit your study for review…
- Return to the workspace of your study. On the right side below My Current Actions, click the Submit link.
• Click the OK button on the Submit pop-up.
• Confirm your login credentials and click OK

If you are NOT the PI send an email to the Principal Investigator to advise them the study is ready for them to review and to submit.

Reliable Methods for Creating a New Study

• A new study is one of the four main forms of submissions in Click IRB. At certain points in the life of a study the other three forms of submissions (continuing review, modification, or RNI (reportable new information) ) may be necessary and will be submitted similarly to a study.

Notes / Other Reliable Methods:

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Assigning Study Team Members, Primary Contact and PI Proxy

Overview

Click is designed so that a study can only be submitted by the Principal Investigator or a study team member who has been identified as a PI Proxy. Click also provides for the assignment of a Primary Contact who receives email notifications about the study.

As a Center Research Associate (CRA) at Seattle Children’s you typically enter and maintain all research information and documentation. So there will be times when you will designate a Primary Contact and/or a PI Proxy other than the PI, in order to facilitate communication and documentation on the study.

The Role of the Primary Contact

The Primary Contact receives email notifications from the IRB, and can edit the study just as a study team member can. The PI continues to receive notifications regardless of the Primary Contact assignment.

By default, the person who created the study in the system is the Primary Contact.

- You can only assign one Primary Contact in Click IRB. The Primary Contact, the PI, and any PI Proxies are the only persons who will receive email notifications.
- For step-by-step instructions on Changing the Primary Contact, see the section later in this workbook on Editing a Draft Study.

Note: Modifications or continuing reviews have the same Primary Contact as the initial study.

The Role of the PI Proxy

The PI Proxy is someone who can submit any/all actions to the IRB on behalf of the PI. The following steps outline the process to follow to assign a PI Proxy when creating a new study in Click:

From the Study Team Members page, click Add.

<table>
<thead>
<tr>
<th>Study Team Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify each additional person involved in the design, conduct, or reporting of the research:</td>
</tr>
<tr>
<td>Add</td>
</tr>
<tr>
<td>Add</td>
</tr>
<tr>
<td>There are no items to display</td>
</tr>
</tbody>
</table>

On the Add Study Team Members pop-up, select yourself (answer the questions appropriately.)

Click OK if you are the only study team member, else choose OK and Add Another to add.
each study team member.

When returned to the Study Team Members page, use the Continue button to navigate through the remaining pages of the SmartForm. On the last page select Save and Close to return to the study workspace.

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

On the Assign PI Proxy pop-up, check the box next to your name

Click OK.

Reliable Methods for Assigning a Primary Contact and PI Proxy

- One bonus of the Click system is that other study team members have access to the study.
- Note: Email notifications are limited to the PI, Proxies, and the designated Primary Contact, but anyone can see the status of the study in the Click system.

Notes / Other Reliable Methods:
Identifying a Funding Source

Overview

The IRB has regulatory responsibilities for certain types of funding. In order to meet those regulatory responsibilities, the IRB collects information about funding sources for studies. To identify funding sources in Click IRB, you will need to know the name of the source(s) and the nature of the funding channel.

To add a Funding Source; click **Add**.

On the **Add Funding Source** pop-up, select the Direct Funding Source, add the award number if known, as well as the Originating Funding Source as needed. Also include the InfoEd ID# if known, and attach the grant application.

Click **OK** if there is only one funding source to add else choose **OK and Add Another** to add additional sources.
Reliable Methods for Identifying a Funding Source

- Ensure you thoroughly search the Organizations list in Click IRB for funding sources.  
  **Tip:** Use a % in the search box as a wildcard cue in order to search on part of the name of the funding source.
- To add an Organization to the list in Click IRB, contact NewClickOrgRequest@seattlechildrens.org. You can expect a response in one full business day.
- New in Click IRB: some sources do not require identification. Read the form carefully.
- For Federal Direct Awards, give the whole grant, not just the research plan.
- Do not use the "Add Related Grant" feature yet.

Notes / Other Reliable Methods:

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Editing a Draft Study

Overview

You may want to open a specific study to view or update its contents, submit it for review, review it, or take other actions on the study.

Note: Your access to a study is personalized based on your role in the system and the role you play in relation to the particular study. In addition, the actions you can take on a study are personalized.

Accessing an Existing Study

<table>
<thead>
<tr>
<th>To access an existing study, <strong>Log in</strong> to the system.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirm that you are in <strong>My Inbox</strong>. <strong>NOTE:</strong> If you do not see <strong>My Inbox</strong>, click the <strong>My Inbox</strong> link in the top right corner of the page.</td>
</tr>
<tr>
<td>Click the <strong>Name</strong> of the desired study to open it.</td>
</tr>
</tbody>
</table>

Changing the Primary Contact

The study's Primary Contact for receiving communications from the IRB can be changed at any time. For example, it may help to provide a contact person in addition to the PI if the PI does not check e-mail frequently.

- To change the Primary Contact, you must be a member of the study team or the IRB coordinator assigned to the study.
- Remember, modifications or continuing reviews have the same Primary Contact as the initial study. To change the Primary Contact on these submissions, do so in the initial study.

<table>
<thead>
<tr>
<th>To change the Primary Contact, from the open study, click <strong>Assign Primary Contact</strong> from the <strong>My Current Actions</strong> list on the left.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A new window opens. Click <strong>Clear</strong> to remove the current contact.</td>
</tr>
<tr>
<td>Begin typing the name of the new contact. A list of matching names appears.</td>
</tr>
</tbody>
</table>
**Step 4**
Select the correct name using the mouse or down arrow key.

**Step 5**
Click OK.

**Note:** If the Primary Contact is also engaged in the research, make sure the list of team members within the study includes the person.

### Revising Existing Supporting Documents

You may modify a study's documents while still in the Pre-Submission state.

**Step 1**
Click **Edit Study** button. The SmartForm opens to Basic Information page.

**Step 2**
Click the **link** to the desired document in the grid to open it.

**Step 3**
Select **Save As** in the pop-up window to save the document.

**Step 4**
Select the location to save the document.

**Step 5**
Select to **Open** the document.

**Step 6**
Make changes, and select **Save**.

**Step 7**
Then click **Update** to open the **Edit Attachment** screen.
Step 8
Browse to the updated file and click OK.

Step 9
Your file is now replaced with the new version.

Reliable Methods for Editing a Draft Study

- You can complete other SmartForm pages as desired while editing your study.
- If you attached a “dummy” or placeholder protocol document with your draft study, be sure to replace it with the final version prior to submitting.

Notes / Other Reliable Methods:

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Submitting a New Study for Review

Overview

After entering all required information into the forms and attaching files, the study is ready to submit for IRB review. Click provides an Automatic System Error Check, which is recommended along with visual inspection of the forms.

Note: The Principal Investigator must submit the study in Click.

Checking for Errors

Checking the study for errors and omissions helps you include all the relevant information, which is critical for receiving a timely review of your study.

Using these types of error checking helps you supply all the information the IRB needs:

• The Automatic System Error Check identifies any omitted answers to required questions on the form when you click Continue. A red asterisk (*) precedes each blank or question that requires an answer. Keep in mind that the system cannot catch every omission while you edit the study if you skip questions that cause more forms to be added to your study.
• Visual Inspection of the forms to see what you may have missed, especially:
  • Questions that are relevant to your study but are not required for all studies
  • Documents that should be attached
  • Using the Hide/Show Errors option to find and correct all errors before submitting the study. The system automatically checks for errors when the PI attempts to submit the study. However, if you are filling out the forms on behalf of the PI, it is best to check the study for errors before the PI submits it, using the steps below.

Step 1
To perform a Visual Inspection, open the study and look through the forms in order.
To use Hide/Show Errors to find and correct errors, open the study.

Step 2
From the menu bar, click Hide/Show Errors.

Step 3
The Error/Warning Messages pane appears at the bottom of the window, listing all the current errors and where to find them. For the errors listed, click the link in the Jump To column to go to the form containing the error.

Step 4
Click Continue to identify the specific questions on the form with errors.
Step 5
Complete the missing information.

Step 6
Click Refresh in the Error/Warning Messages pane to update the list of errors. Continue to rectify until no errors appear.

Submitting for Review
To submit the study for IRB review:

Log in to the system.

Confirm that you are in My Inbox. NOTE: If you do not see My Inbox, click the My Inbox link in the top right corner of the page.

Click the Name of the desired study to open it.

Click Submit from the My Current Actions list on the left.

Click OK to agree to the statement presented on the screen.

When prompted, confirm your credentials to verify your identity.
Click Submit.

NOTE: If one of your study team members does not have a current disclosure on file with the ORC, you will receive the following message:

What to Expect After Submitting

Submitting information to the IRB initiates a series of activities that may include:

- Review within your department
- Pre-review by an IRB staff member
- Review by the IRB committee or a designated reviewer
- Communication of the IRB decision to the investigator

Any of these may lead to a request for the study team to take further action, such as providing clarifications or modifying the study. Whenever the study team needs to act, the PI receives an e-mail notification and the study appears in My Inbox for all study team members when they login to the IRB system. The Pre-Review and Review processes will be discussed in the next training module.

You can view a diagram showing the state of your study within the IRB review process by opening the study. For example:

You can easily open your study from one of the following lists (depending on its status):

- My Inbox
• IRB In-Review Studies
• IRB Active Studies

Reliable Methods for Submitting a New Study

• Create attachments ahead of time (e.g. protocol, consent).
• Carefully read the protocol template and follow the directions for optimal results!

Notes / Other Reliable Methods:

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Submitting External IRB Studies

Overview

Submitting a study to an external IRB (other than NCI CIRB or WIRB) using the Click system requires completing the new study SmartForm, which will route you to an abbreviated form. Be sure to answer yes to question 5 regarding an External IRB, which will pull up the External IRB page and guide you to include approval dates.

For NCI CIRB or WIRB studies, attach the relevant documentation per current business practices in lieu of the reliance agreement.

<table>
<thead>
<tr>
<th>Step</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Start with a consult with the IRB/HSPP Office, unless submitting to NCI CIRB or WIRB.</td>
</tr>
<tr>
<td>2</td>
<td>Obtain Reliance Agreement.</td>
</tr>
<tr>
<td>3</td>
<td>Log in to Click and select Create New Study.</td>
</tr>
<tr>
<td>4</td>
<td>Complete the study SmartForm, responding Yes to question 5 regarding an External IRB.</td>
</tr>
<tr>
<td>5</td>
<td>Follow the prompts in the SmartForm and select Finish to close the form and return to the workspace.</td>
</tr>
</tbody>
</table>

Reliable Methods for Submitting External IRB Studies

- Start with a consult if appropriate.
- Follow up with approval dates and closures.
- Requires a reliance agreement, except for NCI CIRB or WIRB studies.

Notes / Other Reliable Methods:

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Withdrawing a Submission

Overview

Withdrawing a study is initiated by the PI to indicate that the study will not be completed as submitted. As a result of this action, the study is moved back to the pre-submission step.

**Note on Withdrawing versus Discarding:** If the study has previously been submitted to IRB office, it must be withdrawn first before discarding.

To withdraw a submission, on the IRB page find the submission and click the Name link to open the study workspace.

Under My Current Actions, click Withdraw.
On the **Withdraw** pop-up, add any Comments and Supporting documents, click **OK**.

Discontinue the IRB’s review of this submission?
The submission will be returned to the Pre-Submission state where you can choose to change and resubmit it.

**Comments:**

**Supporting documents:**

- Name
- There are no items to display

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**Reliable Methods for Withdrawing a Submission**

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Discarding a Submission

Overview

Discarding is an option for studies in the Pre-Submission state. The result of this action is that the study sits in a discard state. The Discard action is available before submitting the study and not after submitting to the IRB office. After submission, the study must be withdrawn before being discarded.

To discard a submission, on the IRB page find the submission and click the Name link to open the workspace.

From the My Current Actions list, choose Discard.

On the Discard pop-up, click OK.

Reliable Methods for Discarding a Submission
Viewing Disclosure Status

Overview

"Disclosure Status" refers to the financial interests disclosures that all research team members make to the institution. Disclosure is required annually for each person associated with the study. Until a disclosure is completed, final approval of the study could be held up.

There are several status types in Click IRB:

<table>
<thead>
<tr>
<th>If the disclosure displays the following status:</th>
<th>Then consider the disclosure status as:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discloser Review of Plan</td>
<td>Incomplete</td>
</tr>
<tr>
<td>Draft</td>
<td>Incomplete</td>
</tr>
<tr>
<td>In Review</td>
<td>Incomplete</td>
</tr>
<tr>
<td>No Review Required</td>
<td>Complete</td>
</tr>
<tr>
<td>Pending Creation</td>
<td>Incomplete</td>
</tr>
<tr>
<td>Review Complete</td>
<td>Complete</td>
</tr>
<tr>
<td>Under Management Plan</td>
<td>Complete</td>
</tr>
</tbody>
</table>

To view Disclosure Status, begin by opening the study and then go to the **Project Contacts** tab:

Open the study from the list in **My Inbox**.
Click the **Name** of the desired study to open it.
On the study workspace; click the **Project Contacts** tab.

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Financial Interest Review Status</th>
<th>E-mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rebecca Simms (pi)</td>
<td>Draft</td>
<td>testuser@clickcommerc</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study Team</th>
<th>Name</th>
<th>Roles</th>
<th>Financial Interest Review Status</th>
<th>Involved in Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Zahab Ahsan</td>
<td>Draft</td>
<td>Draft</td>
<td>yes</td>
</tr>
</tbody>
</table>

**Reliable Methods for Viewing Disclosure Status**

- ...
- ...
- ...
- ...
- ...
- ...
Managing a Guest List

**Overview**

The Guest List in Click IRB can be used to grant read access to your study to non-study team members, for example Radiation Safety Committee or Clinical Research Center. Read access is limited to the ability to view the study. You must be a study team member to edit, and a PI or PI Proxy to submit a study.

**Note:** SCRI has established a Global Viewer role which enables viewing of all studies, and is available to the Office of Research Compliance and the Institutional Official and designees.

<table>
<thead>
<tr>
<th>To manage a guest list, select the Manage Guest List activity.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manage Guest List</td>
</tr>
<tr>
<td>The following people can view the details of this submission without being on the guest list:</td>
</tr>
<tr>
<td><strong>Principal investigator:</strong> Rebecca Simms (p)</td>
</tr>
<tr>
<td><strong>Primary contact:</strong> Rebecca Simms (p)</td>
</tr>
<tr>
<td><strong>Study team members:</strong> Zahab Ahsan</td>
</tr>
<tr>
<td><strong>Ancillary reviewers for organizations:</strong></td>
</tr>
<tr>
<td>There are no items to display</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Guest list for allowing additional people to view the submission:</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
</tr>
<tr>
<td>------------</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

There are no items to display

<table>
<thead>
<tr>
<th>Select the Add button to open the Select Person list.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select One or More Persons</td>
</tr>
<tr>
<td>Filter by Last  Go  Clear  Advanced</td>
</tr>
<tr>
<td>Deselect All</td>
</tr>
</tbody>
</table>

![Person list](image)

<table>
<thead>
<tr>
<th>Last</th>
<th>First</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>AutomationContactPerson00121106</td>
<td>A Territory Resource</td>
<td></td>
</tr>
<tr>
<td>Automation990Only</td>
<td>Seattle Children’s</td>
<td></td>
</tr>
<tr>
<td>AutomationContactPerson02240746</td>
<td>Abbott Laboratories</td>
<td></td>
</tr>
</tbody>
</table>

Search and select the person’s name then select OK and close the person list.

Select OK again to close the activity.
Reliable Methods for Managing a Guest List

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Final Business Guidance

Thank you for attending this workshop! See below for additional guidance on business practices and reliable methods for Pre-Submission and Submission.

Reliable Methods Overall for Submission

- Create attachments ahead of time (e.g. protocol, consent).
- Carefully read the protocol template and follow the directions for optimal results!
- All protocol-specified drugs must be listed. This means all drugs required by the protocol.
- Most individuals will automatically have access to Click IRB because they have a record in Lawson. If an individual does not have access and needs it, contact the IRB at irb@seattlechildrens.org.
- Pay attention to the disclosure status message upon submission because if anyone on the study team does not have a completed disclosure on file with the institution, then it calls for action by the study team before final IRB approval can be granted.

Notes / Other Reliable Methods:
Glossary of Click IRB Terms

**Checklists:** Documents that provide support for IRB determinations and documentation. The IRB/HSPP Office retains a copy of the final checklist in the protocol file.

**Clarification Requested:** That state of a submission anytime after initial submission where a reviewer has clarifying questions for the research team. This state is close to what we used to call "Pre-Review" (See Pre-Review).

**Continuing Review (CR):** The IRB review of a study conducted at a specified interval (but no longer than 1 year) after initial approval and on an ongoing basis until the study is closed.

**Drugs used in study:** All drugs required by a study protocol. This can include supportive drugs. This does not include drugs that are permissively allowed by the protocol. All drugs meeting this definition must be included in the protocol as well as the consent forms.

**Long Form Consent Documents:** Terminology for what has been our standard consent documents (in contrast to the “Short Form Consent Documents” we are used to).

**Modifications Required to Secure Approval:** Status that IRB gives to a study that requires specific and limited changes in order to obtain final approval. Same status as previous "contingent approval”.

**Non-Committee Review:** Any IRB review that takes place outside the context of a convened meeting, including expedited review.

**Pre-Review:** The review state after initial submission that may encompass the states of Clarification Requested and Submission of the Pre-Review. This term is different from our traditional use of it (see Clarification Requested).

**Regulatory Binder:** This used to be a physical binder that study teams would use to organize and file all study-related documents that they were required to maintain. It is still used as figurative term to represent the entirety of the study team’s files of documents that they are required to maintain (see Investigator Manual).

**Reportable New Information (RNI):** Specified categories of information that are required to be reported to the IRB. Note that some items traditionally reported to the IRB no longer need to be, while others are new.

**Short Title:** Title that will appear on most screens in Click IRB.

**SmartForms:** You prepare a new study for IRB review by entering information into a series of online forms, called SmartForms. The number of SmartForms included changes based on the answers you provide. The forms tell you where to attach files to provide supporting information.

**Worksheets:** Documents that provide support for IRB determinations. Source: Being developed in partnership with Laurie and Tara in the IRB office.