

Click IRB Reference Guide

Choosing a Protocol Template



This guide will help me

- Select a protocol template and will provide guidance on completing it

Step 1	Navigate to the Click IRB library. In general, if your Sponsor has not provided you with a protocol document, you will need to use the protocol templates in the Click IRB library to draft your study protocol. Select the template in the Library that applies to the study. Refer to the Protocol Template Chart (see later in this guide) for help selecting the appropriate template.
Step 2	Save the template from the Click IRB library to your local workstation.
Step 3	Use the regulatory-based checklists found in the IRB Library (under the Checklists Tab) as necessary as you start to prepare the protocol template. Additionally, you can use the protocol worksheets (HRP-308A Protocol or No Contact) to ensure your protocols are complete.
Step 4	Refer to “Key Considerations for IRB Reviews” (later in this guide) for help on successfully completing the Protocol.
Step 6	When modifying the protocol, you can always download the latest approved version from Click IRB. If you keep an electronic copy of your document that you will use to make updates, make sure you are using the correct version before making changes.

Tips on Completing the Protocol Template

- For help in selecting the correct protocol template, schedule a consult with the IRB. A short consult can help get your project on the right track and save you valuable time.
- In cases when you have a template sent to you by the sponsor/coordinating center, attach it, and include the **HRP-508 Site Supplement to Sponsor Protocol**.
- When completing HRP-508, when items are already described in the sponsor’s protocol or other documents submitted with the application, investigators may simply reference the section/page numbers of these documents within the protocol rather than repeat information.
- For multi-center studies where Seattle Children’s is the single IRB of record or the coordinating center, it may be appropriate to attach a protocol that does not use a Click library template along with the site supplement.
- You can upload a “dummy” or placeholder protocol as the attachment in Click IRB if your protocol is in draft at the time you create the study submission. Just make sure you replace it with the final version before you submit.
- Depending on the nature of your research, certain sections of the template may not be applicable to your Investigator Protocol. Indicate this as appropriate. Do not delete sections.

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Protocol Templates Available in the Click IRB Library

Click Number	Title	When should I use this template?
HRP-503	Protocol	Most research studies that do not already have a protocol available from the sponsor
HRP-503A	Protocol - No Participant Contact Protocol	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. Note: This template can sometimes apply to the use of existing materials that were collected for research purposes.
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
HRP-503C	Protocol - Other Status Determination	Projects that you are seeking a determination of not research, not human subjects research, or Seattle Children's is not engaged in a research study (e.g., case reports, QI/QA research) Note: This template is never appropriate for an FDA regulated study
HRP-508	Site Supplement to Sponsor Protocol	Research studies where the sponsor has provided a protocol document for conduct of the study

Key Considerations for IRB Reviews

- 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 these subject populations has regulatory implications.
 - Individuals who are not yet adults (infants, children, teenagers)
 - Adults unable to provide legally effective consent
 - Pregnant women
 - Prisoners
- When the protocol provided by Sponsors/Outside institutions does not provide the required information (see HRP-308A Protocol/No Contact), add the missing elements to HRP-508 Site Supplement to the Sponsor Protocol.
- Read the footnotes/help information provided in the protocol templates-You can “hover” over the citation and the contents of the endnote will appear for you to read

More questions? Contact the Institutional Review Board at irb@seattlechildrens.org or x77804.