INSTRUCTIONS

- Seattle Children's Hospital (SCH) and Fred Hutchinson Cancer Center (Fred Hutch) have an IRB Reliance/Cooperative Review Agreement that allows our institutions to rely on each other's IRB reviews, eliminating the need for duplicate IRB review in most cases.
- Generally, the institution of the **Lead Protocol PI's primary appointment (**i.e., home institution) will serve as the Reviewing IRB for both institutions.
- This form provides guidance to study teams on how to obtain permission to rely on the external IRB (either SCH or Fred Hutch).
- For instructions on how to apply to the Reviewing IRB per standard processes, visit:
    - Fred Hutch IRB – Submissions to the IRB
    - Seattle Children's IRB – See Ext IRB Guide on Click IRB Resources page
- First, confirm both institutions are engaged in research.
- While IRB consultations are not required at either institution, for assistance in determining whether an institution is engaged in research, contact the IRB offices at Fred Hutch or Seattle Children's:
    - Seattle Children's: irb@seattlechildrens.org
    - Fred Hutch: IRO@fredhutch.org

PRELIMINARY CONSIDERATIONS

1. Has the PI confirmed both Fred Hutch and SCH are engaged?

   Yes → Continue to Question 2

   No → Contact your institution's IRB office for assistance in making this determination.

2. Guiding Principle: What is the primary appointment of the Lead Protocol PI?

   Fred Hutch → Seattle Children's will rely on the Fred Hutch IRB. **Go to Section A**

   Seattle Children's → Fred Hutch will rely on Seattle Children's IRB. **Go to Section B**

   Please Note: This guiding principle replaces the previous regarding whether a study was "transplant- related".

Section A — Seattle Children's relies on the Fred Hutch IRB

Before Seattle Children's can be approved as a research location by the Fred Hutch IRB, you must first obtain permission from Seattle Children's to rely on the Fred Hutch IRB. SCH will issue an "Acknowledgement of Reliance on an External IRB" to document this permission.

Prior to Submission to the Fred Hutch IRB

1. Create an External IRB study in the SCH Click IRB system:
    a. Relevant Reference Guides on Click IRB Resources page:
        - *External IRB Studies*
        - *Assigning PI Proxy and Primary Contact*
    b. When choosing Fred Hutch PIs, Primary Contacts, or Study Team Members, only persons who have been onboarded at SCH as credentialed providers, affiliate member (research faculty) or affiliate staff will be available for selection in the SCH Click IRB system.

        Note: For interventional studies, the Lead Fred Hutch PI must be onboarded at SCH.
    c. Only PI or PI Proxies will be able to submit in SCH Click IRB
    d. Only PI, PI Proxies, and the assigned Primary Contact will receive notifications from SCH Click IRB
    e. Fred Hutch individuals can be listed as Primary Contacts in SCH Click IRB without being study team members (as long as onboarded per 1.b. above).
2. SmartForms
    a. Basic Information: List the Lead PI (Study and the Site records)

        Note: If the Lead PI is from Fred Hutch and this individual has not been onboarded at SCH, a local SCH Investigator (i.e., sub-investigator or collaborator) should be selected (for non-interventional studies)

        If there is not a local SCH investigator, the Fred Hutch PI must be onboarded at SCH as noted in 1.b. above.
    b. Study Team Members SmartForm (Site record): Study Team Members should only be listed in Q1 of this form.
        - Include all SCH study team members
        - Include the Fred Hutch study team members who will need to correspond with the SCH IRB regarding reliance and/or to keep the SCH Click IRB study information updated
    c. Documents
        - Required: Protocol (Basic Information SmartForm, Study Record); you may need to submit more as required by the electronic form based on study details (e.g., drug/device information)
        - Not required:
            - Consent Forms are optional as SCH IRB does not review/approve these
            - Documentation of the agreement/reliance
            - HIPAA forms: Fred Hutch will be reviewing associated HIPAA matters

3. Documentation of SCH relying on Fred Hutch
    a. Site will appear as "Pending sIRB Review" state in Click IRB
    b. "Acknowledgement of Reliance on an External IRB" letter will be generated and will appear in Click IRB system
4. Submit to the Fred Hutch IRB per standard process
    a. Ensure Seattle Children's is listed as cancer consortium location on the Local Research Locations SmartForm page in Hutch IRB.
    b. Include a copy of the "Acknowledgement of Reliance on an External IRB" letter issued by SCH IRB with your submission materials to the Fred Hutch IRB.

After Fred Hutch IRB Approval

5. Completing the Submission in SCH Click IRB
    a. Follow the instructions previously provided by the SCH IRB Coordinator to submit the Fred Hutch IRB approval information via SCH Click IRB
    b. A final SCH "Site Approval" letter will be generated and the Site will show as "Review Complete" in SCH Click IRB
6. Update your External IRB Submission in SCH Click IRB over the life of the study
    a. STUDY Record needs to be updated with current approval letters and last day of approval period
        - Study Record updates do not require a Mod submission
        - You should expect to receive CR reminders in Click IRB to update the Study record approval letter and last day of approval period; these are sent 90, 60, and 30 days prior to the date that is filled into the Last Day of Approval period
        - Last day of approval period in SCH Click IRB is NOT the Fred Hutch expiration date, it is the day before the expiration date
        - Other SCH institutional systems (e.g., RSAS) rely upon the data included in the Click IRB system, which if not provided and kept current, may cause challenges for the conduct of the study
        - Do not submit updated protocols as SCH IRB is not requiring changes to protocols over time
        - Request a closure to the study if appropriate; closures cannot be "undone" in Click
    b. SITE Record:
        - Should be updated as changes occur (e.g., changes to study team)
        - Do not submit consents, etc.; SCH IRB is not reviewing these documents

Section B — Fred Hutch relies on Seattle Children's IRB

Before Fred Hutch can be approved as a participating site by the Seattle Children's IRB, you must obtain permission from the Fred Hutch IRO to rely on the Seattle Children's IRB. The IRO will issue an "Endorsement Letter" to document this permission.

Prior to Submission to the Seattle Children's IRB

1. Pre-Submission Considerations
    a. If the funding contract is with Fred Hutch, the contract must be finalized before the IRO will issue an endorsement letter. The IRO facilitates review of the contract against the consent form by Office of General Counsel.
    b. If the funding contract is not with Fred Hutch, the External IRB submission can proceed if the contract is pending.
2. Create and submit an External IRB study in the Hutch IRB system:
    a. Complete the External IRB Supplement, which must be attached to the submission in Hutch IRB (along with any other attachments prompted by the supplement).
    b. Hutch IRB Training resources can be found on the Hutch IRB Training page.
    c. When choosing the PI, Primary Contact, or Study Team Members, only persons who have Fred Hutch or UW credentials and have completed the required System Access Training will be able to *access* Hutch IRB.

    Note: If a Seattle Children's employee needs to be able to view, edit, or submit in Hutch IRB, they must be onboarded at Fred Hutch. For information on obtaining Partner Access, see the instructions on the cancer consortium website.

    Note: To request system access, complete the Hutch IRB Access Request form.
    d. Only the PI or PI Proxies will be able to *submit* in Hutch IRB.
    e. Only the PI, PI Proxies, and the assigned Primary Contact will receive notifications from Hutch IRB.
    f. Seattle Children's individuals can be listed as the Primary Contact in Hutch IRB without being a study team member (as long as onboarded at Fred Hutch per 2.c).
3. SmartForms
    a. Basic Study Information:
        - Select Multi-site or Collaborative
        - Indicate "yes" you are requesting authorization for an external IRB to review the study
        - List the Lead PI (optional) and Local PI (required)

        Note: Generally, the Local PI listed should be the local Fred Hutch investigator, overseeing any Fred Hutch activities. If there is no Fred Hutch investigator, it is acceptable to list the Seattle Children's PI (as long as onboarded at Fred Hutch per 2.c).
    b. Local Study Team Members SmartForm:
        - Study Team Members (Fred Hutch or Seattle Children's) should only be listed if they need access to view, edit, or be added as a PI Proxy in Hutch IRB.
        - Seattle Children's study team members mut be onboarded at Fred Hutch to obtain system access per 2.c.
    c. Local Research Locations SmartForm: Identify each cancer consortium location engaged in the research. You must select both Fred Hutch and Seattle Children's.

d. Documents: You will need to submit the following at a minimum (you may need to submit additional documentation based on study details):

DOCUMENT	WHERE TO ATTACH IN HUTCH IRB
Protocol	Basic Study Information page
Contract (fully executed contract required if Fred Hutch is a signatory)	Study or Local Funding Sources page
If Fred Hutch employees will *not* be consenting: The **study's template consent form**	Study-Related Documents page: – Consent form templates
If Fred Hutch employees *will* be consenting: The Fred Hutch/Cancer Consortium **site-specific consent form**	Local Site Documents page: – Consent Forms
Completed Draft of Seattle Children's IRB application form. Ensure it is clear in the application that the Seattle Children's IRB is asked to review on behalf of Fred Hutch. Note: If Fred Hutch is being added as an amendment to an existing IRB file, include both the initial application and the amendment.	Local Site Documents page: – Other attachments
External IRB Supplement	Local Site Documents page: – Other attachments
HIPAA Authorization	Local Site Documents page: – Other attachments

- Not required:
    - Product information related to drugs/devices (i.e., IBs, package inserts, device manuals)
    - Drug or Device Supplements
    - Contract (if Seattle Children's is the signatory)

4. Administrative review conducted by Fred Hutch IRO
    a. Review of consent form(s) to ensure Fred Hutch consent requirements are included
    b. Confirmation of completed ancillary reviews, as applicable
    c. Facilitation of contract review against consent form by Fred Hutch OGC, if applicable
5. Documentation of Fred Hutch relying on Seattle Children's
    a. "IRO Endorsement" letter will be generated and sent through Hutch IRB.
    b. Site will appear as "Pending sIRB Review" state in Hutch IRB
6. Submit to the Seattle Children's IRB per standard process
    a. Include a copy of the "IRO Endorsement" letter issued by the Fred Hutch IRO with your submission materials to the Seattle Children's IRB

After Seattle Children's IRB Approval

7. Completing the Submission in Hutch IRB
    a. Once the Seattle Children's IRB approves Fred Hutch as a site, provide the following documents using the "Add Comment" activity in Hutch IRB and notify the assigned IRB Coordinator:
        - Study and site approval letter from Seattle Children's IRB

- IRB approved consent forms
- IRB approved protocol (if updated from initial submission in Hutch IRB)

b. A final "Acknowledgement of External IRB Approval" letter will be generated and sent to the PI, Primary Contact, and PI Proxies through Hutch IRB.

c. The External IRB submission will show as "Active" in Hutch IRB

8. Update your External IRB Submission in Hutch IRB over the life of the study

   a. You will receive an automated email notification from Hutch IRB annually to request Continuing Review data, a copy of the Continuing Review approval letter from SCH IRB, and any updates to the record in Hutch IRB.

   b. If Continuing Review is not required by SCH IRB, you will still receive an annual email notification prompting you to confirm the SmartForm and study documents are current in Hutch IRB.

   c. For studies reviewed by an external IRB, Fred Hutch does not generally require modifications be submitted in real-time and can instead be submitted during the annual continuing review process. The exceptions that would require timely notice to the Fred Hutch IRO are:

      - There is a change in Fred Hutch PI – create a Site Modification in Hutch IRB
      - The study has been closed by Seattle Children's IRB – Use the "Add Comment" activity to notify the assigned IRB coordinator and attach closure documentation from Seattle Children's IRB