Implementation Overview

- FH Liaison Role
- Seattle Children’s IRB
- Seattle Children’s Onboarding
- Billing & Merge
- Click IRB
- Pediatric Clinical Research Center (PCRC)
- Research Lab Services (RLS)
- Orders & Requisitions
Fred Hutch Liaison Role

The Fred Hutch / Seattle Children’s Liaison positions help facilitate start-up activities and study implementation within the consortium.
Liaisons

How do I contact a FH Liaison?

- Sheri Ballard (Fred Hutch based)
  [SBallard@fredhutch.org](mailto:SBallard@fredhutch.org)
  ph 667-4222

- Carol Dean (Children’s based)
  [carol.dean@seattlechildrens.org](mailto:carol.dean@seattlechildrens.org)
  ph 987-5790

- CRS Mainline
  [CRSCustomerService@fhcrc.org](mailto:CRSCustomerService@fhcrc.org)
  ph 667-4520
Contact a Research Liaison to set up a study assessment meeting:

- Early in the process is best
- Receive list of steps and timeline to approval
- Get up to date info on processes/contacts
- Schedule meetings (SIV/ PIM, etc) at SCH
- Steps at SCH and FH can be done in parallel
Seattle Children’s IRB

There is a reliance agreement in place that allows Seattle Children’s IRB to accept a Fred Hutch IRB approval.

However…it is more than just a handshake
General Process of Opening A Trial At Seattle Children’s

- Protocol and Submission Documents
- Consult with SCH IRB / Creation in CLICK
- FH Study Team
- SC Staff

Protocol

Send to Clinical Research Budget Analysts (CRBA) – Michelle Palmer

Approved Orders

FH IRB Approval

If PCRC is needed. Submit app. to PCRC

PCRC Approval

FRA is Created/ Finalized; Billing and study code designation set up

FH orders translated for peds

Submit to SC IRB via Click

SC IRB Acknowledges FH IRB Approval

Merge Build

(If applicable) Submit research requisition set up forms: RLS, PCRC, Cardiology, Radiology, Clinic Lab, Radiation Safety, etc (Dept. processes vary)

Research Study Activation Notice (RSAS) is granted

Accrual can begin!
Seattle Children's has cooperative agreements with the following local institutions:

- University of Washington
- Fred Hutchinson Cancer Research Center
- Group Health Cooperative
- Multicare Health System (Mary Bridge Children's Hospital)

These agreements establish IRB review procedures for research involving the respective institutions. Research that can be reviewed under these cooperative agreements can reduce the need for duplicate IRB review.
Avoid dual review whenever possible

The IRB of the prime awardee institution will review for both participating institutions

SC will rely on FH for transplant related studies

FH will rely on SC for studies reviewed by the NCI Pediatric Central IRB (transplant and non-transplant)

Each institution reserves the right to not accept the IRB review of the other and require review by its own IRB
SC IRB – Reliance request

As part of your protocol preparation, we recommend a consult with SCH IRB.

- Send Consultation Request Form to Children’s IRB
- Can be done by study CRA or CRN
- Research Liaison can assist with this process
- Review of research, staff, study funding
If your study is not transplant-related, the SC IRB and the FH IRB have to determine which IRB will be the IRB of record.

- Send an email with your protocol to your institution’s IRB to request review for determining IRB of record
- This will initiate the required institute-to-institute communication
- You will be notified once a decision has been made
- Submit your protocol to the IRB of record
Seattle Children’s IRB requirements for protocol under reliance agreement:

- Consult prior to submission
- Uploading of approval documents/ dates through Click
- List of study staff
- Funding information
- Continuing review documents/ dates
Seattle Children’s Onboarding

Onboarding provides access to SC network (Citrix), Children’s intranet (CHILD), dashboards for tracking studies and patients, and limited patient interaction at Seattle Children’s.
Why do I need Citrix access?

- CIS (electronic medical record)
- CHILD – SC intranet
- Applications for services
- Merge – billing compliance
- Click – electronic IRB tracking
- Online instructions/information (RSAS dashboard)
SC Onboarding

- To start process, contact the **Partner Access Coordinator** to facilitate Partner Access with Seattle Children’s research HR
  - partneraccess@fredhutch.org
  - Cancer Consortium Partner Access page
  - This process is for FH coordinating staff, not credentialed medical providers

- If you have been onboarded but are unable to login to Citrix, your access has expired
  - Contact Partner Access to get your network access renewed
  - This happens if you do not login for a year
What Can FH Personnel do at SC?

- FH personnel can gain access to conduct patient consents, patient interaction/interviews, etc.
- FH personnel cannot gain access to do blood draws, infusions, etc., at this time.
Billing & Merge

All new studies involving human subjects must be reviewed by the Clinical Research Budget Analysts (CRBA) to determine if research billables are present, if the PCRC/RLS is being used, etc.

This is also the hospital mechanism to assure research projects are funded adequately.

Merge CTMS is a Web-based Clinical Trial Management System (CTMS) used to maximizing billing compliance efforts.
Billing & Merge – Overview

- SCCA RIO Submission form and protocol are sent to the SC CRBA (Clinical Research Budget Analysts) from SCCA RIO and/or FH study team.

- The CRBA completes the pricing information for the study events occurring at SC and sends back to the SCCA RIO.

- The protocol is reviewed by the SC CRBA for creation of the FRA (Financial Responsibility Analysis) and Merge entry.

- The FRA is sent to the FH study team for review / approval. Once approved, the study is built in Merge according to the FRA.

- The SC study code is assigned. (RS_FH_2526)

- Once the FRA is approved, an SC Lawson number (internal billing number) will be generated, which will be associated with the study code for SC billing purposes.
What is the FRA?

Financial Responsibility Analysis (FRA): SC document created with input from the study team about what is SOC, Research billable etc.

Who do I contact?

Michelle Palmer, RN, Clinical Research Budget Analyst (Office of Clinical Research Support)

- michelle.palmer@seattlechildrens.org
- ph 884-5617
### Financial Responsibility Analysis

**PI:** McDreamy, Bob  
**Sponsor:** Pharma  
**Study Code:** 123-Study  
**Date:** 3/4/13

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<tr>
<th>Procedures</th>
<th>Cycle 1 Day 1</th>
<th>Cycle 1 Day 4</th>
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<tbody>
<tr>
<td>Serum HCG</td>
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<td>SOC</td>
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<tr>
<td>CBC w/ differential</td>
<td>SOC</td>
<td>SOC</td>
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<tr>
<td>Comprehensive chemistry panel</td>
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<td>SOC</td>
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<tr>
<td>PK samples</td>
<td>Research send out</td>
<td>Research send out</td>
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<tr>
<td>12-lead EKG</td>
<td>SOC</td>
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<tr>
<td>EKG pro-fee</td>
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<thead>
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<tbody>
<tr>
<td>Pharmacy Dispensing</td>
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<td>Research billable</td>
</tr>
<tr>
<td>CRC unit charge, level I</td>
<td>Research billable</td>
<td>Research billable</td>
</tr>
<tr>
<td>CRC unit charge, level V</td>
<td>Research billable</td>
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</tr>
<tr>
<td>PCRC lab processing, routine</td>
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<td>Research billable</td>
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<tr>
<td>PCRC lab, shipping</td>
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<table>
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<tr>
<th>Visit Time Activities</th>
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<td>Adverse event review</td>
<td>Research time</td>
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<tr>
<td>Concomitant med review</td>
<td>SOC</td>
<td>SOC</td>
</tr>
</tbody>
</table>

| CRA                                             |                       |                       |
| Consent verification                             | Research time         | Research time         |
| CRF completion                                  | Research time         | Research time         |

| Research RN                                     |                       |                       |
| Subject education                               | Research time         | Research time         |
Billing - Per Patient Costs

- Procedure costs are non-negotiable

- Determination whether procedures are SOC or research billable is negotiable
Merge

- Merge is a web-based application that Seattle Children’s relies on to track charge direction of research billable events
  - Merge ensures that grants do not pay for SOC items, insurance does not pay for research billables, only one payer is billed, etc.
- You must have Citrix access to get Merge access.
  - If you already have Citrix access, contact Carol Dean to create your Merge account.
How does Merge work?

- Study team finalizes FRA with Michelle Palmer
- Michelle uploads final FRA data into Merge - only visits with research billable events are built into Merge
- When a study participant completes a study visit, log on to Merge and enter visit data (dates, procedures completed, etc.)
- Protocol amendments/study updates – notify Michelle Palmer so the FRA and Merge can be updated
The **Research Study Approval Status** is confirmation of: study code assignment, an executed grant or contract, IRB approval, a linked Lawson billing number, study available in Epic and is ready for research billing and/or scheduling.

* You must check the RSAS dashboard to obtain your RSAS prior to starting enrollment at Children’s

[http://km-tableau/views/RSAS/RSAS](http://km-tableau/views/RSAS/RSAS)
RSAS Dashboard

- If you have SC network access (Citrix), you can see your RSAS status at the RSAS dashboard:
  
  http://km-tableau/views/RSAS/RSAS

- If you do not have SC network access (Citrix), contact Carol Dean to check the dashboard for you
  carol.dean@seattlechildrens.org
The Pediatric Clinical Research Center (PCRC) provides state-of-the-art research space and expertise to investigators conducting patient-oriented research at Seattle Children’s.

Resources include facilities and equipment, as well as experienced staff who are trained in human subjects protection, good clinical practices, protocol implementation and compliance.
Clinical Services - PCRC staff work closely with investigators and study teams throughout the research study process. In addition to providing outpatient services, staff can conduct research activities in hospital areas including inpatient units and other specialty clinics.

- **Nursing**
  - PCRC research nurses implement protocol-specific procedures and provide direct nursing care for patients enrolled in research studies.

- **Medical assistants**
  - PCRC medical assistants (MAs) assist nurses in protocol-related procedures. This includes blood draws, vital signs, EKGs, measurements and specimen collection.

- **Psychometry**
  - A consulting psychologist and research psychometrists are available to assist with study visits involving neuropsychological assessments and specialized cognitive testing. Psychometry visits may be able to take place outside of the PCRC and main hospital campus.
PCRC – Applying for services

To apply to the PCRC you will need:

- Final IRB approval and approved IRB application
- Final IRB stamped Consent/Assent and HIPAA forms
- Study Protocol

Contact Information:

- Phone 206-987-3897
- Email PediatricCRC-ITHS@seattlechildrens.org
The Research Lab Services (RLS) core, operated by the Department of Laboratories, provides an array of laboratory services to support basic, clinical and translational research at Seattle Children’s.
RLS - Services

- Research testing (performed on clinical platforms)
- Specimen processing (centrifugation, PBMC Ficoll, etc.)
- Histology services, including special staining
- DNA/RNA extraction
- Tissue microarrays
- Specimen shipping and storage
- Protocol development and collaboration
- Test development
- Molecular studies
- Thrombin generation assays
- Microparticle/Microvesicle assays

See [RLS Services and Fees](#) for a detailed list of all services
RLS - Contacts

- RLS is located in the PCRC on the 8th floor of the Ocean zone at Seattle Children's main campus

- Staff are available Monday through Friday, 8 a.m. to 6 p.m.

- RLS can be reached at 206-987-1875 or ResearchLabServices@seattlechildrens.org
## Orders & Requisitions

### Research Requisitions

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<th>Title</th>
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<tr>
<td>Admission Research Requisition</td>
<td>03/09/2016</td>
</tr>
<tr>
<td>Audiology Form</td>
<td>08/05/2014</td>
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<td>Cardiology Services Form</td>
<td>02/19/2015</td>
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<tr>
<td>Dental Clinic Form</td>
<td>08/05/2014</td>
</tr>
<tr>
<td>Epic Registration Form (For Outpatient Research Participants)</td>
<td>01/25/2016</td>
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<tr>
<td>GI Lab Form</td>
<td>08/05/2014</td>
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<tr>
<td>Hematology/Oncology Clinic Form</td>
<td>02/10/2016</td>
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<tr>
<td>Laboratory Specimen Removal Request for Non-Clinical Purposes</td>
<td>05/22/2015</td>
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<td>Neurology Services Form</td>
<td>08/05/2014</td>
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<tr>
<td>Nutrition Services Form</td>
<td>03/30/2015</td>
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<td>Occupational/Physical Therapy Form</td>
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<td>Ophthalmology Services Form</td>
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<td>PCRC Neurology Services Form</td>
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<td>PCRC Psychometry Services Research Requisition</td>
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### Resource Categories

- Ambulatory Services
- Building and Engineering
- Clinical Engineering
- Corporate Compliance
- Endocrinology
- Engagement and Recognition
- E-Reporting
- Family Resource Center (FRC)
- Finance
- Foundation
- Health and Patient Education
- Health Information
- Human Resources
- Information Services
- Inpatient
- Inventory and Distribution
- Laboratory
Treatment Orders

- Research medication orders are done on paper at SCH.
- Standard therapy orders may be done electronically.
- Forward protocol and request for order preparation to Carol Dean, and to IDS pharmacist Laura Winter.

- carol.dean@seattlechildrens.org / laura.winter@seattlechildrens.org
How to: Research blood samples collected at Seattle Children’s

- Elements of a Research Sample order
  - Order in CIS
  - Paper requisition
  - Do not give a range of blood to be collected—it is your responsibility to verify what is acceptable to have collected from each patient at the time point requested
  - All studies with research labs need to be set up with RLS, so that samples can be tracked within the hospital
  - Notify lab and staff of sample by sending email
How to: Research blood samples collected at Seattle Children’s

- Research coordinator sends a request to your provider to enter a Research Lab Collection order in CIS

Patient Name: Mario Brother
SCH MRN: 1234567

Specimen type: Blood
Study code: FH5555
Time point: +90
Collection date: 10/31/17
Contact name/#: Jen 555-5555
Comment: On 10/31/17 please collect 6 ml blood in purple tops for FH5555 day +90; send to main lab with research reqs; questions: Jen 555-5555

- All of the red text requires your updated information
Complete the RLS Specimen Transfer Form found on CHILD

The RLS Specimen Transfer Form needs to accompany all of your research blood specimens. It routes the sample to the main lab and informs the lab tech about where to place the specimens for pick up. The lab will not process or charge you or the patient so long as this form is with the specimens.

Send completed form to hemoncCRAs@seattlechildrens.org

Research Staff will print out the form at SCH and get it to the bedside nurse for sample collection. Research staff DO NOT track what happens once the paperwork has been delivered to the bedside nurse.
Submit your completed RLS Specimen Transfer Form to hemoncCRAs@seattlechildrens.org no later than two days prior to date of sample collection

- Hem/onc research staff can accommodate requests submitted one day in advance, if necessary
- Hem/onc research staff cannot accommodate same-day requests

Arrange for specimens pick up (you/study team member) or coordinate with RLS for specimen shipment

- There are fees for using RLS, so please plan accordingly

If immediate sample processing is required, please be sure to coordinate with RLS
After RLS operating hours (M-F, 8am-6pm),

- samples require a study-specific lab requisition so the main lab is able to process.
- RLS will create this requisition for your study

If you use the RLS Specimen Transfer Form in this situation, your sample will not be processed

If you will need sample processing outside of RLS operating hours, please coordinate creation of this requisition by contacting RLS
Requisitions Overview

- Requisitions may be required if your study has special radiology, cardiology, etc. needs

- Clinical lab requisitions are required if you have study specimen needs outside of normal RLS Lab hours (8am-6pm)

- Depts differ on their requisition set-up processes, refer to CHILD for details

- Contact Carol Dean if you need requisitions created that are not supported by the PCRC or RLS
"I think you should be more explicit here in step two."
Consortium Pediatric Protocol Coordinator (CPPC)

Background

- Fred Hutch-based position implemented July 1, 2016
- A result of research integration efforts between Children’s and Fred Hutch

Purpose

- Support and facilitate the initial implementation and ongoing conduct of pediatric studies requiring research services at Fred Hutch/SCCA and Children’s (BMT, Immunotherapy, other “Green Team” research)
- Serve as an initial and stable point of contact for consortium research teams conducting pediatric research at SCCA and Fred Hutch
Services offered

For studies needing implementation at SCCA:

Study planning and start-up at FH/SCCA

- Orientation to clinical and regulatory processes
- Advise protocol development to fit within existing clinical structure
- Determine service areas needed and advise on steps to initiate
- Determine standard care vs. protocol specific procedures
- Participate in SCCA PIM (including assist with RIO submission form)

Study conduct at FH/SCCA

- Guidance/orientation to working with kids at SCCA and working with the outpatient peds teams
- Implementation changes
- Specimen collection coordination
- Troubleshooting and operational problem resolution

Fred Hutch laboratories
Services offered

For studies also needing implementation at Children’s:

• General orientation to conducting research with Seattle Children’s
• Protocol evaluation to determine Children’s service areas needed
• Participate in SCCA PIM process to ensure proper coordination across sites
• Hand-off to FH/SCH research liaison for operational implementation at Children’s
Other Support

• General orientation to doing Consortium research with the peds population
• The interface between Children’s and SCCA/FH
• Special regulatory and clinical concerns/needs when working with pediatric patients
• Other questions and needs pertaining to peds research in the consortium
Contact Info

Sheri Ballard

- Email: sballard@fredhutch.org
- Call: 206-667-4222
- Page: 206-314-0589
THANK YOU