Seattle Children's and Fred Hutch Partnership

From the Research Operations Integration Committee (ROIC) Co-Chairs: Erik Lausund, VP Research Operations & Logistics at Seattle Children's and Kristi Stiffler, VP Clinical Research at Fred Hutch

Tuesday, April 18, 2023

ROIC & Sub-committee Updates:

The Research Affiliation Agreement (RAA) between Fred Hutch and Seattle Children's formalized a governance structure for identifying and resolving issues that impact collaborative research.

ROIC reviews the progress and supports the three sub-committees: data, compliance, and operations.

Research Operations and Integration Committee (ROIC)

- The Research Operations Integration Committee (ROIC) intends to continue providing written updates.
- Please contact the relevant subcommittee co-chairs or the ROIC co-chairs if you identify issues, have questions, feedback, or concerns.

Research Data Governance Sub-committee (RDGS)

- The Research Affiliation Master Data Agreement (RAMDA) which defines the terms by which data is accessed and shared across the institutions, was executed April 1, 2022.
- The RDGS officially convened in May 2022 with a focus on operationalizing the terms of the RAMDA. Data access and use for certain research projects will require the execution of a Data Use Addendum, which provides an opportunity for institutional review and approval of proposed Uses of Health Data, while other projects will not require a Data Use Addendum.
- The Research Data Governance Subcommittee (RDGS) has recently finalized the data request process to facilitate access to data through a standardized process and determine if a Data Use Addendum is required.
- The RDGS has created a **Data Request Workflow** and **FAQs** to provide detailed guidance regarding the process. The **Seattle Children's-Fred Hutch Collaboration Data Request Form** was developed to gather information regarding your data request and to route to the appropriate reviewer and determine if a Data Use Addendum is required. (This form should not be used for clinical trials or Gateway/Atlas data requests.)

Seattle Children's Faculty & Staff	Fred Hutch Faculty & Staff
CHILD Intranet Page	CenterNet Intranet Page
Seattle Children's – Fred Hutch Collaboration Data Request Form	
Data Request Workflow Data Request FAQs	Data Request Workflow Data Request FAQs

Please feel free to reach out to the **RDGS co-chairs** with questions.

Research Compliance Standards and Coordination Sub-committee (RCSCS)

- Training Reciprocity:
  Seattle Children's (SC) and Fred Hutchison Cancer Center (Fred Hutch) have established training reciprocity to allow our institutions to rely on each other's required training programs, thus eliminating the need to complete duplicative training in most cases. The table below outlines training reciprocity and requisite documentation, including required frequency:

Training Type	Reciprocal Acceptance	Need to Send Documentation	Training Frequency
Human Subject Protection (HSP) Training	Yes	Yes (onboarding/renewal)	Every 3 years
Good Clinical Practice (GCP) Training	Yes	Yes (onboarding/renewal)	Every 3 years
Confidentiality, Patient Privacy, HIPAA Training	Yes	No	Annual
Conflicts of Interest (COI) Training	Yes	No	Annual
Bloodborne Pathogens (BBP) Exposure Training	Yes	No	At onboarding/renewal
Equity, Diversity, and Inclusion (EDI) Training	Yes	Attestation Required	Once at Onboarding

- Consortium Policies:
  Since its designation as a National Cancer Institute (NCI) Comprehensive Cancer Center in 1973, the Fred Hutch/University of Washington/Seattle Children's Cancer Consortium has demonstrated a commitment to excellence in cancer research and treatment. The purpose of the Consortium is to bring together cancer-focused researchers from across its three participating institutions, Fred Hutch/University of Washington/Seattle Children's. Through efforts to promote collaboration and support research among its members, the Cancer Consortium aims to increase understanding, strengthen prevention and diagnostic capabilities, and develop effective therapies for cancer. Together we are fostering world-class, state-of-the-art research programs and providing excellent patient-centered care.

  The Cancer Consortium has compiled research support available at our partner institutions that leverage each organization's strengths to further premier research programs across many types of cancer and ensure the development of the next generation of scientists.

  Clinical Research Support oversees a group of resources available to investigators to support their research, simplify processes and enable regulatory compliance. Its mission is to ensure the conduct of efficient, compliant, and high-quality clinical research throughout the Cancer Consortium. In support of that mission, the Consortium has established clinical research policies that guide standardized research practices across all partner institutions.

A National Cancer Institute (NCI) Designated Cancer Center creates a Consortium that binds all members (Fred Hutch/University of Washington/Seattle Children's). This Cancer Center is governed by NCI terms and conditions and must operate in accordance with the Notice of Award. A set of policies were established to ensure consistency with NCI objectives. The purpose and status of each policy is outlined below:

Consortium Policy Title	Purpose
ClinicalTrials.gov Results and Adverse Events Policy	Ensure compliance with Section 801 of the Food and Drug Administration Amendments Act (FDAAA) of 2007 and National Institute of Health (NIH) Policy on the Dissemination of NIH Funded Clinical Trial Information
Consortium Study Coordinator (CSC) Training Policy	Ensure compliance with ICH Good Clinical Practice (GCP) 2.8 which requires individuals involved in conducting a trial be qualified by education, training, and experience to perform his/her respective duties.
Delegation of Authority (DOA) Policy	Ensure compliance with ICH GCP, 21 CFR Section 312.60 and 21 CFR Section 312.3(b)
External Monitoring Reports Policy	Ensure compliance with ICH GCP, 21 CFR Section 312.60, and 21 CFR Part 312.50. Describes how to ensure adequate monitoring of Cancer Consortium clinical trials when the study is not monitored by the Clinical Research Support (CRS) Office to ensure research conducted by Consortium members meet regulatory requirements.
Clinical Research Training Policy	Ensure compliance with GCP and CFR Title 21 and implements GCP training requirement for Consortium investigators and staff.
Inspection and Sponsor Audit Notification Policy*	Describes notification steps to be taken by study teams upon learning of an FDA inspection or Sponsor audit of a Consortium clinical trial. Supports CCSG requirement to subject all clinical protocols to a protocol review and monitoring system.
Scientific Review Committee (SRC) Low Accrual Policy	Outlines the process by which Cancer Consortium clinical trials are reviewed and evaluated by the SRC for possible closure to further accrual due to poor accrual. NOTE: Trials that enroll pediatric patients are Exempt.
Review of Safety Reports Policy	Addresses requirements for Consortium Principal Investigator (PI) review of Safety Reports of individual adverse events. Allows investigators to fulfill obligations to protect the rights, safety, and welfare of human subjects and comply with institutional review board (IRB) reporting requirements related to unanticipated problems, while reducing review of reports that are issued by the sponsor without sufficient information for an individual investigator to make a meaningful assessment.
Principal Investigator Leave Policy	Instructs PI delegation of oversight responsibilities to a qualified individual during their absence. Describes documentation of delegation and acceptance of responsibilities and that notification is provided to the IRB of record and to the study sponsor, when applicable.

*Policies that are newly drafted

Clinical Research Operations Sub-committee (CROS)

- The CROS working group has been making progress to finalize the **Affiliate Member** onboarding process at Seattle Children's and Fred Hutch. Investigators will be able to affiliate at the "host organization" and access their resources and facilities (network and badge access). The new application will launch April 2023.
- The CHILD page has been updated for Seattle Children's based investigators and staff to learn more about the Fred Hutch Research Partnership and view past communication newsletters

Thank you for helping us with this collaborative partnership!

Issues, questions, or feedback? Please reach out & connect --

Committee Membership & Contact Information

Committee	Name	Email
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