FRED HUTCH UNIVERSITY OF WASHINGTON CANCER CONSORTIUM	**Clinical Research Policies and Procedures**
	Consortium Study Coordinator Training

Approval			
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Background

ICH Good Clinical Practice 2.8 states that each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective tasks(s).

The Consortium Study Coordinator (CSC) Training Curriculum was designed to provide clinical research staff with consistent, foundational knowledge and information needed to conduct clinical research within the Cancer Consortium. Personnel engaged in clinical research must have the appropriate training to perform their assigned duties to help ensure regulatory compliance, data integrity, and the protection of the rights, safety, and welfare of research subjects.

This policy describes the Consortium training requirements for new and existing clinical research staff involved in the design, conduct or reporting as identified through Consortium CTMS access requests. This policy does not cover additional institutional, department, or operational training that may also apply e.g., Good Clinical Practice, Human Subjects Training or HIPAA.

Responsible Personnel

Principal Investigator

Clinical Research Managers and Staff

Abbreviations and Acronyms

CSC: Consortium Study Coordinator

CRS: Clinical Research Support

CTMS: Clinical Trial Management System

FH/FHCRC: Fred Hutch/Fred Hutchinson Cancer Research Center

ICH: International Council on Harmonisation

GCP: Good Clinical Practice

HSP: Human Subjects Protection

LMS: Learning Management System

PI: Principal Investigator

SC: Seattle Children's

SCCA: Seattle Cancer Care Alliance

UW: University of Washington

Definitions

Cancer Consortium: An NCI-designated Comprehensive Cancer Center comprised of Fred Hutch (FH), University of Washington (UW), Seattle Children's (SC), and Seattle Cancer Care Alliance (SCCA).

Clinical Research Staff: Individuals involved in the design, conduct, and/or reporting of a clinical trial and to whom a PI delegates study related duties. Examples of Consortium research staff required to complete the CSC Training curriculum include clinical research coordinators, research nurses, managers, data coordinators, regulatory coordinators, managers, research assistants or any other role with similar job functions.

Conduct: Implementation and management of research involving human subjects. Staff members conducting research include principal investigators, research staff working on a research study, and others engaged in research activity supporting the research study (i.e., conducting interviews, surveys, data collection).

Consortium PI: Principal Investigator who is a member of the Cancer Consortium and is the responsible leader of the team for a study conducted by a group of individuals at a study site.

Consortium Study Coordinator (CSC) Training Curriculum: A collection of online training modules developed by the Clinical Research Support (CRS) Training Program to establish foundational training for Consortium clinical research staff.

Design: developing the research concept, scientific method, or objectives for a study that involves intervention or interactions with a human subject or the use of identifiable data or tissue derived from a human subject.

Learning Management System (LMS): A software platform used for the central management and delivery of learning content within an organization.

Reporting: analyzing, summarizing, or preparing manuscripts involving data derived from a research study involving human subjects.

Policy

Clinical research personnel involved in the design, conduct or reporting of an interventional clinical trial or prevention trial testing the use of an FDA-regulated drug, biologic or device must complete the CSC Training curriculum delivered through the CRS Training Program.

Procedures

General Requirements:

New and existing Consortium research personnel involved in the design, conduct or reporting of an interventional clinical trial or prevention trial testing the use of an FDA-regulated drug, biologic or device who submit a request for CTMS access will be required to complete the CSC Training Curriculum in addition to the system training prior to gaining access.

The CSC Training Curriculum will be assigned, tracked, and maintained electronically through the Hutch Learning LMS. When research personnel submit a request for CTMS access, CRS will confirm the required training is complete.

Consortium research managers and PIs will be responsible for ensuring that their research staff fulfill these training requirements regardless of prior research experience.

Applicable Regulations & Guidelines

ICH Guideline for Good Clinical Practice E6(R2)