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Sponsor Nora Olsen: NE Research Monitor
Area Cancer Consortium - Institutional
Applicability FHCC Institutional Policies

Clinical Research Training Requirements

SCOPE:

This policy applies to all Fred Hutchinson Cancer Center (Fred Hutch), University of Washington (UW), and Seattle Children's (SC) workforce members supporting Cancer Consortium clinical research activities.

PURPOSE:

The U.S. Food and Drug Administration (FDA) Code of Federal Regulations (CFR Title 21) requires that investigators (and study personnel) be qualified (through education, training, and experience) to perform their assigned clinical trial duties. In addition, IRBs, sponsors, and funding agencies may require training for researchers. For example, the NIH requires investigators and all key personnel who will be involved in the design or conduct of NIH-funded human subjects research to fulfill the protection of human subjects education requirement.

Good Clinical Practice (GCP) is an international ethical and scientific standard for conducting biomedical and behavioral research involving human participants. This standard provides assurance that the rights, safety, well-being, and confidentiality of trial participants are protected, and that the data and reported results of clinical trials are accurate. Adherence to the principles of GCP is internationally recognized as a requirement for the conduct of research involving human subjects and has been adopted as official FDA guidance.

Human Subjects Protections (HSP) is a collective term for the federal, state, and university policies, procedures, and ethical considerations that protect the rights and welfare of human beings who participate in research as the subjects of that research. Human subjects protections include, among other elements, oversight by an institutional review board or equivalent ethics committee and adherence

to an informed consent process that is designed to inform potential participants of the voluntary nature of research participation and other information they need when deciding whether to participate in clinical research.

This policy document implements the GCP and HSP training requirements for investigators and personnel involved in the design, conduct, or reporting of a Cancer Consortium therapeutic interventional clinical trial or prevention trial regardless of the Principal Investigator's institutional primary appointment or the IRB of record for a particular study.

DEFINITIONS:

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

Cancer-related Study: A study that meets one or more of the following characteristics:

- Funded by NCI; or
- Primary site of a multi-site trial has classified the study as cancer or cancer-related; or
- The trial cohort will include both patients with a cancer diagnosis and others without a cancer diagnosis AND includes a primary or secondary analysis of the portion of the cohort with a cancer diagnosis; or
- Research of secondary conditions related to cancer treatment in patients with a cancer diagnosis who have received that treatment; or
- Cancer prevention studies that specifically include a primary outcome of cancer diagnosis; or
- Bone Marrow Transplant (BMT) not related to cancer treatment.

Clinical Trial: Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s). Also referred to as **Clinical Study** or **Research Study**.

Code of Federal Regulations: The Code of Federal Regulations (CFR) annual edition is the codification of the general and permanent rules published in the Federal Register by the departments and agencies of the [United States] Federal Government.

Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

POLICY:

Investigators and personnel involved in the design, conduct, or reporting of a cancer-related clinical trial must have current GCP and HSP training if they are employees of a Consortium institution or if they are employees of a non-Consortium institution and involved in the design, conduct, or reporting of a Cancer Consortium clinical trial.

REQUIREMENTS:

Accepted GCP and HSP training courses include:

- CITI online course (www.citiprogram.org);
- Trainings designed and offered by the Consortium Institutions;
- GCP or HSP training offered by institutes within the NIH; and
- Other equivalent GCP or HSP training provided by an industry sponsor or other organization may be accepted. Upon request, Clinical Research Support (CRS) will review the training and determine whether the course is acceptable.

Refresher GCP and HSP training are required at a minimum of once every three years (date based on most recent training rather than anniversary of initial training date).

Investigators and personnel who do not meet the training requirements may not be involved in the design, conduct or reporting of a Consortium clinical trial. Clinical Research Support (CRS) will notify the employee and the employee's supervisor or Division Director if the job description requires GCP and HSP training so that the employee can complete the required training or modify their responsibilities so they do not require GCP and HSP training.

If personnel supporting trial conduct at a non-Consortium institution require GCP and HSP training according to this policy, the Consortium Investigator must ensure these personnel have completed an accepted form of GCP and HSP training and provide documentation to Clinical Research Support prior to initiating trial activities at that institution. If the non-Consortium institution represents a site conducting the trial under the oversight of a PI at that institution, the Consortium Investigator must ensure the PI and lead research coordinator have completed an accepted form of GCP and HSP training and provide documentation to Clinical Research Support prior to activating the trial at that institution.

If the Investigator or study personnel fail to meet the training requirements, the Clinical Research Oversight Committee (CROC) may close the study to further accrual until training requirements have been met.

Examples of personnel required to complete GCP and HSP training include principal investigators, sub-investigators, research nurses recording participant data, research coordinators responsible for evaluating laboratory results or completing case report forms, statisticians involved in the interpretation of data during the conduct of the trial, staff members involved in the conduct of the trial (including responding to operational issues such as protocol violations, conducting site training, or advising sites in data management), and research managers who may not be involved in the actual conduct of the trial but are instead responsible for protocol management (i.e., developing and designing Case Report Forms required by the protocol).

REFERENCES:

ICH Guideline for Good Clinical Practice E6(R2)

NIH Notice NOT-OD-00-039, *Required Education in the Protection of Human Research Participants.*

NIH Notice NOT-OD-16-148, *Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials*.

Title 21 of the Code of Federal Regulations, Parts 50, 56, 312, and 812

Approval Signatures

Step Description	Approver	Date
	Natalie Simpson: Policy & Practices Mgr	04/2023
	Kristi Stiffler: VP, Clinical Research	04/2023
	Nora Olsen: NE Research Monitor	04/2023