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| Clinical Research Oversight Committee Chair | Fred Hutch | Date: | 12/7/16 |
| Vice Dean, Research and Graduate Education, School of Medicine, University of Washington | UW | Date: | 12/5/16 |

## Background

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.

The 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 GCP training for researchers.

The Cancer Consortium IRB requires GCP training for all FHCRC personnel involved in the conduct, reporting or evaluation of a cancer-related clinical intervention or prevention trial testing the use of an FDA regulated drug, biologic or device.

This policy document implements the GCP training requirement 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.

## Responsible Personnel

Principal Investigator

Medical Director, Clinical Research Support

Director, Clinical Research Support

Quality and Compliance Manger, Clinical Research Support

## Abbreviations and Acronyms

CFR: Code of Federal Regulations

CITI: Collaborative Institutional Training Initiative

CRS: Clinical Research Support

CROC: Clinical Research Oversight Committee

FDA: Food and Drug Administration

FHCRC: Fred Hutchinson Cancer Research Center

GCP: Good Clinical Practice

ICH: International Council on Harmonisation

IRB: Institutional Review Board

NCI: National Cancer Institute

NIH: National Institutes of Health

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, University of Washington (UW), Seattle Children's (SC), and Seattle Cancer Care Alliance (SCCA).

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).

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.

Consortium Institutions: Fred Hutch, University of Washington, Seattle Cancer Care Alliance, Seattle Children's

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

Therapeutic Interventional Trial: Studies in human beings in which individuals are assigned by an investigator based on a protocol to receive therapeutic interventions. The protocol is designed to evaluate one or more interventions for treating a disease, syndrome or condition. Such interventions may be either biomedically or behaviorally based. The assignment of the intervention may or may not be random. The individuals are followed and biomedical and/or health outcomes assessed.

## Policy

Investigators and personnel involved in the design, conduct or reporting of a therapeutic interventional clinical trial or prevention trial testing the use of an FDA-regulated drug, biologic or device must have GCP 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 an FDA-regulated Cancer Consortium clinical trial where the sponsor-investigator is a Cancer Consortium member.

## Procedures

Accepted GCP courses include:

- CITI online course (www.citiprogram.org): Basic Course in Good Clinical Practice;
- GCP training offered by institutes within the NIH; and
- Other equivalent GCP 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 training is required at a minimum of once every three years (date based on most recent training rather than anniversary of initial training date).

A lapse in refresher training of more than six (6) months will require a repeat of complete GCP training rather than refresher training.

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.

If personnel supporting trial conduct at a non-Consortium institution require GCP training according to this policy, the Consortium sponsor-investigator must ensure these personnel have completed an accepted form of GCP 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 sponsor-investigator must ensure the PI and lead research coordinator have completed an accepted form of GCP 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 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).

Examples of Consortium personnel generally not required to complete GCP training include data entry staff members who do not analyze or exercise judgment regarding the data, research lab staff, programmers, and administrative staff.

## Applicable Regulations & Guidelines

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

ICH Guideline for Good Clinical Practice E6

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

## Attachments / Related References

Cancer Consortium Institutional Review Office Policy: Training Policy 2.20

| Version Review History | |
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| **Reviewer** | **Date** |
| Frederick Appelbaum, MD, Deputy Director, FHCRC | 5/20/2014 |
| Frederick Appelbaum, MD, Deputy Director, Fred Hutch | 12/7/2016 |
| John Slattery, PhD, Vice Dean, University of Washington | 12/5/2016 |