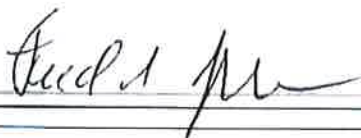



Approval

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| Version: | 2.0 | | |
| Effective Date: | 6/5/2017 | | |
| Last Reviewed Date: | 5/31/2017 | | |
| Original Approval Date: | 5/20/2014 | | |
| Clinical Research Oversight Committee Chair or Designee |  | Date: | 5/31/17 |
| Printed Name | Frederick Appelbaum, MD | | |
| Vice Dean, Research and Graduate Education, School of Medicine, University of Washington |  | Date: | 6/9/17 |
| Printed Name | John T. Slattery, PhD | | |

Background

FDA regulations and ICH Good Clinical Practice guidelines hold the Principal Investigator (PI) responsible for the conduct of a study. Title 21 CFR Section 312.60, *General responsibilities of investigators*, states:

An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation.

Section 4 of the ICH Guideline for Good Clinical Practice (GCP) further details investigator responsibilities.

The study sponsor has responsibilities for the conduct of a clinical trial distinct from those of the investigator. In order to assure appropriate conduct of clinical research studies, FDA regulations and ICH GCP define monitoring as one of the responsibilities of the study sponsor. Title 21 CFR 312.50, *General responsibilities of sponsors*, states in part:

Sponsors are responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND [...]

ICH Good Clinical Practice guideline 5.18 also hold the sponsor responsible for ensuring that the trial is adequately monitored. The guideline states:

The purposes of trial monitoring are to verify that:

- (a) *The rights and well-being of human subjects are protected.*
- (b) *The reported trial data are accurate, complete, and verifiable from source documents.*
- (c) *The conduct of the trial complies with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirements(s).*

This policy describes how Clinical Research Support (CRS) will help to ensure that the study sponsor fulfills their responsibilities of adequately monitoring Cancer Consortium clinical trials when the study sponsor is not a Cancer Consortium member and therefore, not monitored by CRS. These reports will provide information to CRS committees tasked with ensuring that research conducted by Consortium members adequately meets regulatory requirements.

Responsible Personnel

- Principal Investigator
- Medical Director, Clinical Research Support
- Director, Clinical Research Support
- Quality and Compliance Manager, Clinical Research Support

Abbreviations and Acronyms

- CFR: Code of Federal Regulations
- CROC: Clinical Research Oversight Committee
- CRS: Clinical Research Support
- DSMC: Data and Safety Monitoring Committee
- FDA: Food and Drug Administration
- FHCRC: Fred Hutchinson Cancer Research Center
- GCP: Good Clinical Practice
- ICH: International Council on Harmonisation
- PI: Principal Investigator
- SC: Seattle Children’s
- SCCA: Seattle Cancer Care Alliance
- UW: University of Washington

Definitions

Clinical Trial: Any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes. (ICMJE)

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| <p>FRED HUTCH UNIVERSITY OF WASHINGTON CANCER CONSORTIUM</p> | <p>Clinical Research Policies and Procedures Study Documentation</p> |
| | <p>Submission of External Monitoring/Auditing Reports for Clinical Research Studies</p> |

Cancer Consortium: An NCI-designated Comprehensive Cancer Center comprised of: Fred Hutchinson Cancer Research Center (FHCRC), University of Washington (UW), Seattle Children’s (SC), and Seattle Cancer Care Alliance (SCCA).

Investigator: The responsible leader of the team for a study conducted by a team of individuals at study site. (21 CFR 312.3(b))

Sponsor: A person who takes responsibility for and initiates a clinical investigation. The sponsor may be a pharmaceutical company, a private or academic organization, or an individual. (21 CFR 312.3(a))

Policy

When an investigator is serving as Principal Investigator of a Cancer Consortium FDA-regulated clinical trial and the study sponsor is not a Cancer Consortium member and therefore, not monitored by CRS, the PI is required to submit copies of all monitoring and auditing reports from the sponsor to CRS.

Procedures

The PI is responsible for ensuring that all monitoring and auditing reports, summaries, and/or post-monitoring visit letters generated by non-Consortium sponsors are sent electronically to CRS. The reports can be sent to CRS via the following methods:

- Email reports to CRSQuality@fredhutch.org
- Ask the Sponsor or CRO to add CRSQuality@fredhutch.org to the distribution list
- If the Sponsor or CRO requires an individual for a distribution list, provide contact information for the CRS Quality Program Manager.

Reports will be reviewed by the Consortium’s Compliance Sub-Committee, a subcommittee of the Consortium’s Data and Safety Monitoring Committee (DSMC). The Subcommittee helps to ensure that the sponsor is fulfilling its monitoring responsibilities and to ensure that the investigator and study personnel are conducting the study in accordance with applicable guidelines and regulations.

Detection of substantial failure to submit monitoring and auditing reports in accordance with this policy, evidence of repeated or significant findings in the reports or evidence of inadequate monitoring by the sponsor may result in escalation to the appropriate review body for further action.

Applicable Regulations & Guidelines

21 CFR Part 312

ICH GCP 5.18

Attachments/Related References

21 CFR Part 312

ICH GCP 5.18

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| Version Review History | |
|---|------------|
| Reviewer | Date |
| Frederick Appelbaum, MD, Deputy Director, FHCRC | 05/20/2014 |
| Frederick Appelbaum, MD, Deputy Director, FHCRC | 05/31/2017 |
| John T. Slattery, PhD, Vice Dean for Research, University of Washington | 05/31/2017 |