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Background

FDA regulations and ICH Good Clinical Practice guidelines hold the Principal Investigator (PI) ultimately responsible for the conduct of the 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.*

21 CFR Section 312.3(b) and GCP section 1.34 further define the investigator as "the responsible leader of the team" for a study conducted by a team of individuals at a study site. The PI may delegate specific tasks to appropriately qualified and trained members of this team, but remains fully accountable.

In reference to delegation itself, a 2009 FDA guidance on Investigator Responsibilities states:

> *The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task. Appropriate delegation is primarily an issue for tasks considered to be clinical or medical in nature.*

In reference to documenting delegation of authority, this FDA guidance states:

> *The investigator should maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated. This list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform delegated tasks (e.g., can refer to an individual's CV on file), and*

identify the dates of involvement in the study. An investigator should maintain separate lists for each study conducted by the investigator.

Per ICH GCP 4.1.5, "the investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties." This may include individuals who do not contribute directly to conduct of the study and do not need to be named on the protocol and/or 1572, such as individuals submitting regulatory documents or performing data entry.

Documenting how authority to carry out specific tasks is delegated is one of the ways in which an investigator demonstrates a plan to ensure that a study is conducted according to the protocol and other requirements, that the well-being of participants is protected, and that investigational agents will be controlled. Therefore, it is essential that delegation of authority be appropriately documented and that this documentation is maintained throughout the life of the study.

This policy document describes how investigators should document delegation of authority on all Cancer Consortium therapeutic interventional and/or FDA-regulated clinical trials. By following this policy, investigators will ensure their compliance with institutional policy and federal law and reduce the risk of a major finding during routine monitoring or a formal regulatory inspection.

This policy is consistent with the FDA Guidance for Industry *Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects (October 2009)*, which describes the FDA's expectations for appropriate supervision of a clinical trial, including oversight of study staff and other individuals contributing to conduct of the study, and delegation of study-related tasks.

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

CRS: Clinical Research Support

DOA: Delegation of Authority

FDA: Food and Drug Administration

FHCRC: Fred Hutchinson Cancer Research Center

GCP: Good Clinical Practice

ICH: International Council on Harmonisation

IDE: Investigational Device Exemption

IND: Investigational New Drug

LIP: Licensed Independent Practitioner

NCI: National Cancer Institute

PI: Principal Investigator

SC: Seattle Children's

SCCA: Seattle Cancer Care Alliance

UW: University of Washington

UWMC: University of Washington Medical Center

Definitions

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.

Licensed Independent Practitioner: Any individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges.

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. The assignment of the intervention may or may not be random. The individuals are followed and biomedical and/or health outcomes assessed.

Policy

Principal Investigators are required to document delegation of authority as described in this policy statement when conducting a Cancer Consortium therapeutic interventional and/or FDA-regulated clinical trial.

Procedures

General Requirements:

A study-specific delegation of authority log must be completed and kept up to date. This log should include sub-investigators, study staff, and any individuals to whom significant study-specific clinical or medical responsibilities are delegated. CVs (and licenses, if applicable) should be on file for all individuals on the DOA log, demonstrating their qualifications. The Consortium will accept CVs with typed or handwritten dates.

Each entry must list responsibilities and tasks that person may perform and include start and end dates for the individual's involvement with the protocol. Each entry must be signed by the person to whom responsibilities are delegated and must be initialed and dated by the PI. Entries should be updated in real-time.

Inclusion on the delegation of authority log is not typically required for individuals providing routine patient care at SCCA and/or UWMC who are not acting outside their normal scope of duties, are not conducting study-specific activities, and do not make a direct or significant contribution to the clinical study data.

Clinical and laboratory departments that provide ancillary research services such as study drug infusion and/or specimen collection and processing may in certain instances be represented on the DOA log by obtaining the signature of managerial or supervisory staff member(s) who take accountability for training and performance within the department.

Requirements for Documenting Licensed Independent Practitioners Conducting Informed Consent Discussions for Therapeutic Interventional Trials:

Attending physicians, fellows, and other Licensed Independent Practitioners (LIPs) at SCCA conduct informed consent discussions on numerous protocols in the course of their routine clinical responsibilities. Standard institutional practices ensure that LIPs have the necessary study-specific knowledge to fulfill this responsibility. PIs and study team personnel communicate directly with LIPs regarding study treatments and participants. In addition, LIPs are educated regarding protocol-specific regimens, risks, and benefits via established SCCA structures such as patient care conferences, when the proposed course of treatment for individual patients is discussed. LIPs are recognized as being authorized to obtain informed consent, unless otherwise specified by individual protocols. However, because the informed consent process is fundamental to the conduct of all clinical research, specific documentation of delegation of this responsibility is required. LIPs delegated to obtain informed consent do not need to be listed as sub-investigators on Form FDA 1572 unless they are also providing a direct and significant contribution to the clinical data.

- For clinical trials conducted under an IND or IDE, delegation of authority for the informed consent process may be documented by one of two methods:

    1. LIPs who may be reasonably anticipated to obtain protocol-specific informed consent from study participants may be included on the delegation log, with signatures and PI certification obtained before participation in study activity.

    2. LIPs may be added to the delegation log after obtaining consent from subject to participate in a study. The start date of study responsibility will be the date of consent. A memo clarifying this practice will be placed in the study regulatory binder.

- For interventional clinical trials *not* conducted under an IND or IDE, delegation of authority for the informed consent process may be documented by either of the methods used for trials conducted under an IND or IDE, or by the following method.

    A central signature log for LIPs who may be reasonably anticipated to obtain protocol-specific informed consent from study participants may be maintained within individual research programs according to the following guidelines:

    - A master log containing the printed names, "wet ink" signatures, dates, and initials of each LIP will be maintained in a central binder for the research program.

    - An individual, study-specific cover sheet identifying relevant LIP activities (e.g., informed consent) and signed by the Principal Investigator will be placed in each individual study binder with a photocopy of the

master log. In this case, any updates to the master log must be copied to the study binder, and the study-specific cover sheet must be updated accordingly.

- The PI must initial and date the study-specific cover sheet to acknowledge the change when a new LIP is added to the master log.

Requirements for Documenting Investigational Drug Services Pharmacy Personnel:

Delegation of drug accountability activities to the SCCA and/or UW Investigational Drug Services (IDS) pharmacies should be documented by the addition of IDS Pharmacists to the delegation of authority log. Pharmacy Technicians are not required to sign the delegation of authority log.

Failure to document or maintain delegation of authority in accordance with this policy, or evidence of inappropriate delegation of authority, may result in escalation of the finding to an appropriate review body for further action.

Applicable Regulations & Guidelines

ICH GCP 4.1.5

FDA Guidance for Industry: Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects (October 2009)

Attachments/Related References

ATTACHMENTS

Delegation of Authority Log template

Delegation of Authority Log instructions

Documentation of Delegation of Authority for Informed Consent Note to File

Version Review History	
Reviewer	**Date**
Frederick Appelbaum, MD, Deputy Director, FHCRC	5/20/2014
Frederick Appelbaum, MD, Deputy Director, FH	5/31/2017
John T. Slattery, PhD, Vice Dean for Research, University of Washington	5/31/2017