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Area Cancer Consortium - Institutional
Applicability FHCC Institutional Policies
References Org Wide/ Institutional

Delegation of Authority for Clinical Research Studies

SCOPE:

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

PURPOSE:

This policy describes how investigators should document delegation of authority on all Cancer Consortium interventional trials and/or FDA-regulated clinical trials. Such documentation may involve the use of electronic signatures and electronic records when used in compliance with 21 CFR Part 11 and with all applicable Cancer Consortium policies and procedures. 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, auditing, or a formal regulatory inspection.

U.S. Food and Drug Administration (FDA) regulations and International Council for Harmonisation (ICH) Good Clinical Practice (GCP) 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 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.

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 Research Support (CRS):** Fred Hutch-based department providing central management and oversight functions for coordinating, facilitating, and reporting on the Consortium's clinical research.
- **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 (CFR):** 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.
- **Delegation of Authority (DOA):** A mechanism for contemporaneously tracking appropriately qualified individuals to whom the investigator has delegated significant trial-related roles and responsibilities. Also, Electronic Delegation of Authority (eDOA).
- **Good Clinical Practice (GCP):** An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.
- **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.
- **NCI:** National Cancer Institute

POLICY:

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

A study-specific delegation of authority (DOA) log must be completed and kept up to date. This log should include:

- The Principal Investigator,
- sub-investigator(s),
- study staff, and
- any clinical providers or other individuals to whom significant study-specific responsibilities are delegated.

CVs (signed and dated electronically, in wet ink, or a combination of both), licensure (if applicable),

Human Subjects Protection (HSP) training (every three years), and GCP training (every three years) should be on file for all individuals on the DOA log, demonstrating their qualifications.

Study-Specific DOA Log: Each study-specific DOA log entry must list an individual's name, their role on the study, the study-specific tasks that person may perform, and the start date for the individual's involvement with the protocol. Each entry must be initialed (or signed) and dated by the PI. Acceptance of the delegated tasks must be indicated by the designee's dated signature on either the study-specific DOA log entry and/or on a separate list of study tasks (e.g., the *Study Staff Qualification Page*) that they are deemed qualified to perform based on education, training, experience, scope of work, and licensure or certification (where applicable).

- Cooperative Group trials should use the Delegation of Tasks Log format as directed by CTEP.

Study Staff Qualification Page (SSQP): An employee-specific SSQP may be completed to identify an individual's role and describe the research tasks that they are deemed qualified to perform based on education, training, experience, scope of work, and licensure or certification (where applicable). A designee who signs a SSQP may perform those tasks on any given study after completing protocol-specific training (if applicable) and being delegated by the PI on the study-specific DOA log.

DOA Documentation Methods: DOA documentation may be created and maintained on paper or electronically; if electronically, a system compliant with FDA regulations under 21 CFR Part 11 (*Electronic Records; Electronic Signatures*) is required for studies that are subject to FDA regulation. Any study that transitions from paper to electronic DOA documentation during its course must either retain the original paper documentation for the full term of other record retention on the study, or follow a Cancer Consortium-approved policy for scanning and destruction of the paper records.

Inclusion on the delegation of authority log is not typically required for individuals providing routine patient care at FH and/or UW who are not acting outside their normal scope of duties (e.g., infusion nurses, radiology technologists), are not conducting study-specific activities, and do not make a direct or significant contribution to the clinical study data.

Requirements for specific roles and service areas:

Sub-investigators: A sub-investigator is an individual who makes a "direct and significant contribution to the clinical data" based on the study tasks delegated by the PI. This includes performing significant study activities such as determining study eligibility and assessing adverse events. Individuals in this role must be identified on the study-specific DOA log as sub-investigators, maintain current study-specific training, and be listed on Form FDA 1572 and complete financial disclosure forms when applicable to the study.

Providers obtaining informed consent: Attending providers at FH may conduct informed consent discussions on numerous protocols in the course of their routine clinical responsibilities when permitted by the IRB-approved consent process identified for applicable protocols. Standard institutional practices ensure that providers who will obtain informed consent have the necessary study-specific knowledge to fulfill this responsibility. PIs and study team personnel communicate directly with providers regarding study treatments and participants. In addition, providers are educated regarding protocol-specific

regimens, risks, and benefits via established FH structures such as patient care conferences, when the proposed course of treatment for individual patients is discussed. Obtaining informed consent in this scenario is not considered a "direct and significant contribution to the clinical data." However, because the informed consent process is fundamental to the conduct of all clinical research, study-specific documentation of delegation of this responsibility is required and may be documented by one of two methods:

1. Providers who may be reasonably anticipated to obtain protocol-specific informed consent from potential study participants may be included on the study-specific DOA log prospectively, with PI authorization documented before participation in study activity. Provider acceptance of the delegated task may be documented on the study-specific DOA log or via the SSQP.
2. Providers may be added to the study-specific DOA log after obtaining consent from a potential study participant. The start date of study responsibility will be the date of consent.

Providers prescribing investigational product (IP): FH attending providers associated with transplant or cellular immunotherapy services (e.g., as identified on the FH "Bellboy" document) may prescribe IP on numerous protocols in the course of their routine clinical responsibilities when prescribing is authorized by the PI, is based on an ordering plan previously approved by the PI, and is *not* prohibited by the protocol. The investigator must ensure that the PI or a delegated, clinically qualified sub-investigator has previously confirmed the study participant's eligibility, that each study participant is assigned to the correct treatment arm and dosing level (when applicable), and that the approved ordering plan for the protocol contains adequate instructions for the provider to determine that administration of the IP is in accordance with the approved protocol and does not represent undue risk to the study participant. The role of the attending physician requires direct, ongoing oversight of the clinical care for all patients on the assigned service, including study participants. Therefore, when the PI fulfills the above requirements to ensure that only eligible participants (as assessed by the PI or authorized sub-investigator) are able to receive the IP, the attending physician is in the most appropriate position to assess the participant's immediate clinical status and issue the prescription based on providing direct care to the study participant.

Prescribing IP in this scenario is considered part of the attending physician's clinical role and is not considered a "direct and significant contribution to the clinical data." However, because prescribing IP involves a critical responsibility for subject safety, study-specific documentation of delegation of this responsibility is required and may be documented by one of two methods:

1. Providers who may be reasonably anticipated to prescribe IP may be included on the study-specific DOA log prospectively, with PI authorization documented before participation in study activity. Provider acceptance of the delegated task may be documented on the study-specific DOA log or via the SSQP.
2. Providers may be added to the study-specific DOA log after prescribing IP to a study participant. The start date of study responsibility will be the date of the prescription.

Investigational Drug Services Pharmacy Personnel: Delegation of drug accountability activities to Investigational Drug Services (IDS) pharmacies should be documented by the addition of IDS Pharmacists to the DOA log. Pharmacy Technicians are not required to be included on study-specific

DOA logs or to complete SSQP documentation.

Personnel Providing Ancillary Research Services: Departments that provide ancillary research services such as study drug infusion and/or specimen processing may, in certain instances, be represented on the DOA log by managerial or supervisory staff member(s) who take accountability for training and performance within the department.

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.

REFERENCES:

- *FDA Guidance for Industry: Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects (October 2009)*
- *ICH GCP 4.1.5*
- *Title 21 CFR Part 11 (Electronic Records; Electronic Signatures)*
- *Title 21 CFR Part 312 (Investigational New Drug Application)*

Approval Signatures

Step Description	Approver	Date
	Natalie Simpson: Policy & Practices Mgr	02/2025
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	Nora Olsen: CR Reg Affairs&Compliance Dir.	02/2025

Applicability

FHCC Institutional Policies