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

Principal Investigator On Leave

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 International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines and the U.S. Food and Drug Administration (FDA) regulations hold the Principal Investigator (PI) responsible for the conduct of a study. The Code of Federal Regulations (CFR) Title 21 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 GCP further details investigator responsibilities.

In order to effectively fulfill these responsibilities, the PI must be available on a consistent basis for activities such as study team oversight, subject eligibility review, assessment of safety information, clinical management of study-related adverse events, adjudication of protocol compliance, and other direct involvement. The PI must ensure these responsibilities continue to be met in the event that the PI is not personally available.

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**.
- **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.
- **Leave of Absence:** An excused period of time off work.
- **Sponsor-Investigator:** An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

POLICY:

A PI who is not available to directly oversee research conduct for an extended period of time must delegate oversight responsibilities to a qualified individual during their absence. The PI must ensure that delegation and acceptance of responsibilities are specifically documented, and that notification is provided to the institutional review board (IRB) of record and to the study sponsor, when applicable. Specific requirements for documentation and notification are determined primarily by the duration of PI absence.

This policy is not intended to apply to limited, routine absences such as vacations, conference attendance, or minor illness.

REQUIREMENTS:

PI Absence of Less than Three Months

A temporary PI leave of absence (less than three months), where a complete return to duties is expected, typically does not require a formal modification submitted to the IRB or alterations to the Form FDA 1572 (Statement of Investigator). IRB of Record and sponsor requirements should be consulted to ensure that policies do not conflict. It is acceptable to document that a current sub-investigator will take over PI responsibilities in the interim. A Note to File (NTF) or equivalent memo must be prepared for each study affected, that includes the language noted in *PI on Leave NTF* template. This NTF must be signed by both the PI and the sub-investigator providing interim coverage, submitted to the IRB of record and to the study sponsor (if applicable), and retained in the study regulatory binder. The PI is responsible for ensuring that the designated sub-investigator has up-to-date protocol training and has all necessary coverage responsibilities assigned on the delegation of authority log.

If the NTF regarding coverage did not specify when the PI would return, the PI should sign an additional NTF documenting resumption of responsibilities upon return.

PI Absence of Three Months or Longer

In the event of a LOA for three months or longer, a qualified on-site sub-investigator should be appointed as PI by formal modification to the study. The interim PI will assume all PI responsibilities during the absence of the original PI. Modifications to the study and all applicable documents (i.e., informed consent) should be submitted to the IRB for the change to the interim PI prior to implementation and for the reinstatement of the original PI upon return. Whenever possible, the change of PI should be submitted to IRB before the LOA goes into effect. If the outgoing PI is unavailable to endorse the change of PI, the applicable Division Director or Designee should sign off on the transfer of responsibility.

If the study is conducted under an investigational new drug application (IND), the interim PI should sign a new Form FDA 1572 (Statement of Investigator) assuming responsibility as the PI and submit the 1572 to the IND sponsor. If the study is conducted under an investigational device exemption (IDE), the interim PI should sign applicable documentation assuming responsibility as the PI per the direction of the IDE sponsor and submit the documentation to the IDE sponsor. When the PI on LOA returns and resumes their role as PI, a new Form FDA 1572 should be signed and submitted to the sponsor. If the PI on LOA is Sponsor-Investigator of an IND or IDE, the FDA and CRS Regulatory Affairs should also be notified of the temporary transfer of sponsor responsibilities.

In the event of a PI leave of absence, the PI should also work with the appropriate divisions, departments, and grants management to identify and address potential impacts on funding agreements, industry contracts, and the transfer of research records and funds. Relevant institutional offices may include:

- Fred Hutch Conflict of Interest Office
- SC Human Resources
- UW Office of Sponsored Research
- UW Clinical Research Budget & Billing (CRBB)

REFERENCES:

- CFR Title 21
- ICH Good Clinical Practice Guidance (E6)

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