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Fred Hutch IDS Pharmacy Clinical Research Training Requirements

SCOPE:

This policy applies to all Fred Hutchinson Cancer Center ("Fred Hutch") Investigational Drug Services (IDS) Pharmacy Workforce Members who perform investigational product management and related clinical research activities.

PURPOSE:

The purpose of this policy is to establish guidance regarding the training requirements for IDS Pharmacy staff conducting clinical research activities. This document clarifies regulatory expectations and organizational standards related to IDS Pharmacy personnel training in accordance with Good Clinical Practice (GCP) and applicable FDA regulations.

DEFINITIONS:

- **Investigational Product**: A drug or biological product that has not yet been determined to be safe and effective for a particular use in the general population and not yet approved by the Food and Drug Administration (FDA) for commercial marketing.
- **Investigator**: A person responsible for the conduct of the clinical trial, including the trial participants for whom that person has responsibility during the conduct of the trial. If a trial is conducted by a team of individuals, the investigator is the responsible leader of the team and

may be called the principal investigator.

- **Investigator's Brochure (IB)**: A compilation of the clinical and nonclinical data on the investigational product(s) that is relevant to the study of the investigational product(s) in human participants.

POLICY:

IDS Pharmacy personnel receive training proportionate to their specific role and responsibilities, which may include review of relevant safety and product-specific information. IDS Pharmacy staff conducting clinical research activities complete (per IDS SOP and Cancer Consortium policy):

- Good Clinical Practice (GCP) training and Human Subjects Protection (HSP) training.
- Protocol-specific training, consisting of initial and amended protocols and pharmacy manuals.
    - Sponsor-provided training slide decks reviewed for Site Initiation Visit (SIV) purposes only.
- Investigational product information training.
    - Product-specific safety information relevant to pharmacy duties.
    - Labeling, packaging, and storage requirements.
    - Handling of investigational product in trial context.

This training is sufficient to ensure IDS Pharmacy staff are adequately informed about relevant aspects of the protocol, the investigational product(s), and their assigned trial activities.

IDS Pharmacy staff performing clinical research activities do not require separate, dedicated training on the Investigator's Brochure, which is designed primarily to ensure the investigator is familiar with the appropriate use of the investigational product(s). IDS Pharmacy staff roles focus on product management (storage, handling, dispensing, accountability) rather than clinical safety assessment or investigator-level decision-making.

REFERENCES:

- U.S. Food and Drug Administration. *Code of Federal Regulations, Title 21, Part 312—Investigational New Drug Application.*
- U.S. Food and Drug Administration. *E6(R3) Good Clinical Practice (GCP).* Federal Register, September 2025.