Status **Active** PolicyStat ID **15202356**

Effective	02/2024
Next Review	02/2027

Sponsor	Kristi Stiffler: Vice President, Clinical Research
Area	Cancer Consortium - Institutional
Applicability	FHCC Institutional Policies
References	Org Wide/ Institutional

Research Participant Withdrawal

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 purpose of this policy is to outline which research activities, data collection, and data retention are permitted and which are prohibited following study participant withdrawal from a clinical trial conducted within the Fred Hutch/UW/Seattle Children's Cancer Consortium (Consortium).

A participant enrolled in a research study may decide to withdraw from the research, or an Investigator may decide to terminate an individual's participation in a research study, at any time. The International Council for Harmonisation (ICH) Guideline for Good Clinical Practice requires that informed consent and the written informed consent form include an explanation:

> *That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.*
>
> – ICH E6(R2) Section 4.8.10(m)

U.S. federal regulations on the Protection of Human Subjects include equivalent requirements and further require that, when appropriate to the study context, informed consent include:

> *Anticipated circumstances under which the subject's participation may be terminated by the investigator*
>
> and
>
> *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject*
>
> – 45 CFR 46.116(c); 21 CFR 50.25(b)

DEFINITIONS:

- **Cancer Consortium**: An NCI-designated Comprehensive Cancer Center that comprises Fred Hutchinson Cancer Center (Fred Hutch), 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 Staff**: Individuals involved in the design, conduct, and/or reporting of a clinical trial and to whom an investigator delegates study-related duties. May also be referred to as **Study Team.**
- **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.
- **Withdrawal from study intervention**: Study treatment/intervention stopped earlier than specified in protocol (e.g., did not complete specified number of cycles or time frame; not withdrawn for toxicity or progression reasons described in protocol). Participant will continue with some or all study follow-up activities.
- **Withdrawal from intervention and procedures**: Study treatment/intervention either stopped early or completed per protocol. Participant does not want some or all follow-up visits/ procedures as described in protocol, but allows contact and/or medical record review by study

team for follow-up information.

- **Withdrawal of consent/Withdrawal from follow-up**: Study treatment/intervention either stopped early or completed per protocol; participant does not permit contact or medical record review. Study team review of public records for survival status is permissible unless the participant has specified in writing that no follow-up is allowed.

POLICY:

When a participant is withdrawn from a clinical trial prior to completing all study procedures and/or follow-up, the individual's rights must be protected, and their preferences respected whenever possible, regarding any subsequent activities, direct contact, indirect contact (such as medical record review or updates from other individuals known to the participant), or data collection related to the study. This requires that the participant be given relevant information about use of existing data and about study withdrawal options and that they have the opportunity to communicate preferences to the study team.

The participant's decision to accept or refuse certain types of follow-up activity should be documented. When a participant's decision cannot be documented, decisions about follow-up activities should prioritize the individual's safety and right to privacy. For example, it may be appropriate to notify a withdrawn participant about a newly identified late toxicity for which they should be clinically monitored.

This policy describes the required, recommended, and permitted activities associated with a participant's withdrawal from participation in a clinical investigation prior to completing the activities described in the protocol. This may occur based on either the participant's or the Investigator's decision. This policy does not apply to withdrawal based on protocol specifications (e.g., due to unacceptable toxicity as described in the protocol).

Withdrawal Information Provided to Study Participants

The following information must be provided in the informed consent discussion and informed consent form prior to study participation:

- the participant may choose to withdraw from the study at any time (all studies),
- anticipated circumstances under which the Investigator may withdraw the participant from the study regardless of the participant's consent (when applicable to the study), and
- consequences of a participant's decision to withdraw from the study and procedures for orderly termination of participation (when applicable to the study).

The following additional information is recommended:

- whether data collected prior to the participant's withdrawal will remain in the study records (note: for FDA-regulated studies, data collected prior to the participant's withdrawal *must* remain in the study database),
- whether data will be collected from private sources following the participant's withdrawal (e.g., follow-up contact with participant, family, or health care providers; review of medical records), and

- whether data will be collected from public records following the participant's withdrawal (note: FDA specifically permits review of public records for information such as survival status without obtaining the participant's explicit consent).

Requirements at the Time of Participant Withdrawal

For voluntary or investigator-initiated participant withdrawal from the study:

- *before study treatment and all follow-up safety monitoring are complete*, the Investigator or a delegated, clinically qualified sub-investigator must promptly discuss with the participant the decision to withdraw, reason for withdrawal, and anticipated clinical implications. The discussion must be documented in the patient's medical record and the study record.
- *after protocol-required safety monitoring is complete*, the Investigator or a delegated member of the study team must discuss with the participant the decision to withdraw. The discussion must be documented in the study record; documentation in the patient's medical record is optional.

Withdrawal Options (Requires discussion) The Investigator or a delegated member of the study team must explain withdrawal options as appropriate to the study and the participant's time point in completing the study. These may include, but are not limited to:

- Withdrawal from study intervention
- Withdrawal from intervention and procedures
- Withdrawal of consent/Withdrawal from follow-up

Discussion of Prior Consent (Recommended) It is recommended that the Investigator or a delegated member of the study team review relevant information from the most recently signed informed consent form with the withdrawing participant, if the form included information about data retention following withdrawal and/or other information about activities following withdrawal.

These discussions and the participant's preferred option for withdrawal must be documented in the participant's study record and may be documented in the medical record.

If the participant declines to discuss their specific withdrawal preferences and does not respond to related follow-up requests and communications, the study team shall make no further contact or obtain information via medical records. Public records searches are allowed.

Public Records

Review of public records for information such as survival status is typically permitted when performed by study staff or other Consortium personnel who are authorized to obtain survival data on study participants. The following are prohibited:

- Participant information will not be released to outside entities such as industry sponsors or third-party "patient finder" services.
- Public records searches are not permitted when a participant has specified in writing that no follow-up contact or review of medical records is allowed.

Hospice Care

Research participants who have transferred to hospice care will be considered withdrawn from study intervention, procedures, and direct contact. If the participant has not indicated an intention to withdraw, study team may continue to obtain information via medical records or other providers. In individual circumstances, participant involvement may continue at PI's discretion.

Withdrawal of Minor Participants

In the event of any discrepancy between this policy and Seattle Children's policies on research participants who are minors at the time of study withdrawal, Seattle Children's policies will apply.

REQUIREMENTS:

- *U.S. Code of Federal Regulations Title 21 Part 50 (Protection of Human Subjects)*
- *U.S. Code of Federal Regulations Title 45 Part 46 (Protection of Human Subjects)*

REFERENCES:

- *FDA Guidance for Sponsors, Clinical Investigators, and IRBs — Data Retention When Participants Withdraw from FDA-Regulated Clinical Trials (October 2008)*
- *HHS Guidance on Withdrawal of Participants from Research: Data Retention and Other Related Issues (September 21, 2010)*
- *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)*

Approval Signatures

Step Description	Approver	Date
	Natalie Simpson: Policy & Practices Mgr	02/2024
	Kristi Stiffler: Vice President, Clinical Research	02/2024
	Kristi Stiffler: Vice President, Clinical Research	02/2024
	Nora Olsen: CR Reg Affairs&Compliance Dir.	02/2024

Applicability

FHCC Institutional Policies