Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Diversity in Clinical Trials
Version:	1.00
Effective Date:	January 1, 2026
Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

POLICY STATEMENT

The purpose of this policy is to ensure clinical trials conducted at Fred Hutchinson Cancer Center (Fred Hutch) adhere to Revised Code of Washington (RCW) 69.78 and comply with federal regulations, including the Food and Drug Administration (FDA) and the department of Health and Human Services (HHS) guidelines. RCW 69.78 emphasizes the need for diverse participation in clinical trials to enhance the quality and applicability of data regarding the safety and efficacy of interventions (social, behavioral, and medical) across various demographic groups.

DEFINITIONS

See *HRP-001 - Glossary of Terms and Acronyms* for full definitions of the following:

Clinical Trial

Electronic Informed Consent (e-consent)

Remote Consent

Underrepresented community or underrepresented demographic group

PRINCIPLES/OVERVIEW

Investigators conducting clinical trials at Fred Hutch should aim to promote the inclusion of underrepresented demographic groups in clinical trials, address barriers to participation, and support the Belmont Principle of Justice by supporting equitable representation and access.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to IRO staff, IRB members, and investigators who submit to the Fred Hutch IRB.

PROCEDURES

Principal Investigators submitting to the Fred Hutch IRB must describe their plans for inclusion and recruitment of any known underrepresented demographic groups as part of their initial submission to the IRB. Investigators will be prompted to consider the following topics when completing *HRP-250 - FORM - IRB Application (Contact)*.

1. Enrollment Targets

a. Projected Enrollment Targets

The Fred Hutch IRB expects all studies to collect demographic data such as ethnicity, race, and gender. Investigators are asked to project their anticipated local enrollment based on these

categories at the time of their initial submission to the IRB. Investigators should consider the following when projecting their local enrollment targets:

- What is the basis for the proposed ethnic and racial enrollment targets?
- What is the plan for collecting demographic data?
- What is the plan for recruiting under-represented demographic groups if a disease disproportionately affects certain populations, or if the study examines health disparities?

Investigators are encouraged to contact the Office of Community Outreach & Engagement (OCOE) for assistance with setting appropriate enrollment targets.

For oncology trials, investigators may also review OCOE's regularly issued Community Health Assessment Reports that assess the burden of cancer in Washington state and identify community health needs.

For clinical trials with non-Fred Hutch-based participants or healthy volunteers, use appropriate sources to reflect the cohort identification (e.g., King Country demographic data, U.S. Census, World Health Organization, etc.).

b. Monitoring of Enrollment

At the time of Continuing Review, investigators are expected to report actual enrollment numbers for the year, broken down by ethnicity, race, and gender. If a study is not on track to meet local ethnicity, race, and gender goals described in the initial IRB application, the investigator must describe a plan for how the study will meet these enrollment goals within the upcoming approval period or provide a robust justification for a change to the initial accrual targets.

The IRB will consider the investigator's plan and may refer an investigator to consult with the Office of Community Outreach & Engagement (OCOE) to develop a recruitment strategy.

2. Community Collaboration

For research aimed at addressing problems within a specific community or demographic group that historically is underrepresented in research or historically bears worse disease burden or outcomes, researchers should work with the Office of Community Outreach & Engagement (OCOE) to engage community collaborators to support equitable and inclusive research practices. Collaboration can occur along a spectrum of involvement, from one-time consultations to full community-led community-based participatory research (CBPR). Greater engagement with community partners from groups that are underrepresented in research will support research that is equitable and inclusive.

- Examples Include:
  - **Focus groups** to prioritize study goals and refine design, data collection, and/or results dissemination plans.
  - **Community advisory boards** to provide ongoing study guidance.
  - **Partnerships** with community-based organizations to co-develop and conduct studies.
  - **Collaborations** with existing groups representing historically excluded populations.
  - **One-time or repeated consultations** with community members for feedback on study design, recruitment, and retention plans.

For community-based participatory research, investigators should describe in the initial IRB application or protocol how community members and organizational representatives will be involved in the research process and well as any processes to provide community members with reports on the progress, interim results, or final results during or after the research.

Successful community engagement requires long-term investment of effort, time, and resources by the research enterprise. These relationships are most effective when they are part of a long-term strategy of engagement and dialogue rather than on project-specific needs. Community collaboration may not be feasible for all clinical trials, such as pilot projects or early phase studies being conducted solely within the Fred Hutch clinic.

3. Language Access

It is the policy of Fred Hutch that non-English speaking participants are afforded the opportunity to participate in research with appropriate protections in place, including interpretation and translation services to facilitate the proper communication of information to participants.

Investigators may encounter research participants who are not English speakers, or may engage in research studies that target individuals who are not English speakers. It is the Principal Investigator's (PI) responsibility to ensure that non-English speakers are presented with the same opportunity to participate research as individuals who are fluent in English. Any plan to exclude non-English speakers from the research must be justified and approved by the IRB. Allowable justifications for excluding non-English speakers from participant in a specific research study are detailed in *HRP-129 – POLICY – Use of Interpreter Services and Translated Documents*.

When non-English speakers are included in research, the investigator must describe how the team will communicate with the non-English speaking participants during the course of the research (e.g., interpretation services or study staff who speak the native language) as part of the initial IRB application. Investigators should ensure availability of bilingual staff and interpretation services for trial screening, information, and ongoing communication.

The Fred Hutch Interviewing, Translation and Interpretation Services (ITIS), part of the Shared Resources Collaborative Data Services (CDS) group, is available to translate into Spanish and to coordinate translation requests for other languages with existing vendors.

Fred Hutch has allocated some institutional funds to assist in covering translation costs for studies that do not have budget allocated for translations. Fred Hutch investigators may apply for these funds by completing the Translation Bridge Funding Request Form.

4. Electronic and Remote Consent and Study Procedures

When making enrollment decisions, participants need to consider the logistics of being able to complete the study procedures. This includes: 1) the location of recruitment activities and study procedures; 2) the days of the week and hours of the day that are available for participation; and 3) the frequency of study visits and total time commitment.

Investigators should consider whether offering remote consent and/or electronic consent options can help reduce barriers to participation.

Investigators must describe their consenting plan in the initial IRB application. If conducting consent remotely, investigators should describe in detail how consent will be documented, referring to *HRP-090 – POLICY – Informed Consent* for consent expectations.

Electronic consent tools must be approved by the IRB prior to use. Fred Hutch offers both an FDA Part 11 validated e-consent tool and non-Part 11 validated e-consent tools. See *HRP-090 – POLICY – Informed Consent* to determine the most appropriate option based on which regulations apply.

Additionally, investigators should also consider whether it is feasible to allow flexibility in study procedure scheduling; to offer parking, childcare or other supportive services to support study participation; and whether some study procedures could be undertaken remotely or at a lab more convenient to participants (for example, offering remote administration of questionnaires or the possibility of a study blood draw at a participant's local lab). Such provisions should be described in the initial IRB application or protocol.

SUPPORTING DOCUMENTS

HRP-090 – POLICY – Informed Consent

HRP-129 – POLICY – Use of Interpreter Services and Translated Documents

HRP-250 - FORM - IRB Application (Contact)

REFERENCES

RCW 69.78 Diversity in Clinical Trials

VERSION HISTORY

Version	Effective Date
1.00	01-01-2026