

SENATE BILL REPORT

2SHB 1745

As Passed Senate - Amended, April 12, 2023

Title: An act relating to improving diversity in clinical trials.

Brief Description: Improving diversity in clinical trials.

Sponsors: House Committee on Appropriations (originally sponsored by Representatives Thai, Duerr, Doglio, Ormsby and Macri).

Brief History: Passed House: 3/6/23, 95-0.

Committee Activity: Health & Long Term Care: 3/17/23, 3/23/23 [DPA-WM].
Ways & Means: 3/30/23, 4/03/23 [DPA, w/oRec].

Floor Activity: Passed Senate - Amended: 4/12/23, 49-0.

Brief Summary of Bill (As Amended by Senate)

- Establishes a diversity in clinical trials program at the Washington State Institutional Review Board.
- Requires any state entity or hospital receiving funding from the National Institutes of Health to conduct clinical trials of drugs or medical devices to adopt a policy concerning recruitment of persons who are members of underrepresented demographic groups, provide information in languages other than English, and to provide translation services.
- Requires investigators in clinical trials undertaken by state entities or hospitals to collaborate with community-based organizations.
- Requires the Andy Hill Cancer Research Endowment Program to consider factors related to an applicant's ability to increase the diversity of participants in clinical trials when awarding grants.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not part of the legislation nor does it constitute a statement of legislative intent.

Majority Report: Do pass as amended and be referred to Committee on Ways & Means.

Signed by Senators Cleveland, Chair; Robinson, Vice Chair; Rivers, Ranking Member; Muzzall, Assistant Ranking Member; Conway, Dhingra, Holy, Padden, Randall and Van De Wege.

Staff: Kevin Black (786-7747)

SENATE COMMITTEE ON WAYS & MEANS

Majority Report: Do pass as amended.

Signed by Senators Rolfes, Chair; Robinson, Vice Chair, Operating & Revenue; Mullet, Vice Chair, Capital; Wilson, L., Ranking Member, Operating; Gildon, Assistant Ranking Member, Operating; Schoesler, Ranking Member, Capital; Rivers, Assistant Ranking Member, Capital; Warnick, Assistant Ranking Member, Capital; Billig, Boehnke, Braun, Conway, Hasegawa, Hunt, Keiser, Muzzall, Nguyen, Pedersen, Torres, Van De Wege and Wagoner.

Minority Report: That it be referred without recommendation.

Signed by Senators Dhingra, Saldaña and Wellman.

Staff: Monica Fontaine (786-7341)

Background: The Washington State Institutional Review Board. An institutional review board is a federally-mandated entity that reviews research proposals to assure the rights and welfare of human subjects are protected, risks to human subjects are minimized and not unreasonable, and that proposed study designs and methods are appropriate.

The Washington State Institutional Review Board (WSIRB) is the designated institutional review board for several state agencies, including the Department of Social and Health Services, Department of Health, Health Care Authority, and Department of Labor and Industries. WSIRB provides regulatory review, approval, and oversight of research that involves state agency clients, beneficiaries, patients, wards, and employees. WSIRB ensures the protection of human research subjects and maintains guidelines addressing various topics related to clinical trials.

Clinical Trials. Clinical trials are research studies involving human volunteers to evaluate medical products like medications, vaccines, or medical devices for safety and effectiveness. In 2016, the United States Food and Drug Administration released a guidance document containing nonbinding recommendations for the collection of race and ethnicity data in clinical trials. The guidance addresses ways to collect more consistent demographic subgroup data by establishing minimum standards for maintaining, collecting, and presenting data on race and ethnicity.

Andy Hill Cancer Research Endowment. The Andy Hill Cancer Research Endowment, also

known as the Andy Hill CARE Fund, makes grants to public and private entities for the promotion of cancer research. Requests for funding must be evaluated based on a variety of factors, including:

- the quality of the proposed research or program;
- the potential to improve health outcomes of people with cancer;
- the potential to provide additional health care benefits or benefit other diseases or conditions;
- the potential for leveraging additional funding;
- the potential to stimulate life science, health care, and biomedical employment in Washington;
- the geographic diversity of grantees;
- evidence of potential commercialization-related revenue; and
- evidence of public and private collaboration.

The Andy Hill Cancer Research Endowment is governed by a 13-member board and administered by a private, non-profit corporation with expertise in conducting or managing research granting activities, funds, or organizations. Andy Hill was a member of the Washington State Senate from 2011 until his death from lung cancer in 2016. The Andy Hill Cancer Research Endowment was established by state legislation in 2015, and renamed after Andy Hill in 2018.

Summary of Amended Bill: WSIRB must establish a diversity in clinical trials program to encourage participation in clinical trial of drugs and medical devices by persons who are members of demographic groups underrepresented in clinical trials. WSIRB must compile and share information and resources in an accessible fashion to assist entities in Washington State that conduct clinical trials with increasing diversity of participation, including::

- information concerning methods for identifying and recruiting persons who are members of underrepresented groups to participate in clinical trials;
- links or copies of outside resources related to increasing participation by members of underrepresented groups provided by community organizations or other interested agencies or parties;
- contact information for community organizations or other appropriate entities which may be able to provide assistance with efforts to increase participation by members of underrepresented groups in clinical trials; and
- links to websites maintained by medical facilities, health authorities, and other local governmental entities, nonprofit organizations, and scientific investigators and institutions that are performing research related to drugs or medical devices in Washington State.

Any state entity or hospital that receives funding from the National Institutes of Health (NIH) to conduct clinical trials of drugs or medical devices, including the University of Washington (UW) and Washington State University (WSU), must adopt a policy concerning identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials. Investigators conducting clinical trials

must collaborate with community-based organizations and use methods to recruit persons who are members of underrepresented demographic groups to participate in clinical trials recognized by the United States Food and Drug Administration. These entities must also provide information to trial participants in languages other than English, provide translation services or bilingual staff for trial screening, provide culturally specific recruitment materials alongside general enrollment materials, and provide electronic consent when not prohibited by the granting entity or federal regulations.

The factors considered by the Andy Hill Cancer Research Endowment (Andy Hill CARE) program when evaluating requests for grant funding, proposals, and submissions must include:

- the ability to offer trial participants information in a language other than English;
- the ability to provide culturally specific recruitment materials alongside general enrollment materials;
- the ability to provide electronic consent when not prohibited by other granting entities or federal regulations; and
- other evidence of outreach and engagement to increase participation of underrepresented communities in clinical trials of drugs and medical devices.

The Department of Health (DOH), in consultation with UW, WSU, Andy Hill CARE, Washington community health boards and initiatives, community-based organizations, and other relevant research organizations, must analyze and provide recommendations on matters related to increasing participation by underrepresented groups in clinical trials and provide a report to the Legislature by December 1, 2023.

Starting January 1, 2024, UW and WSU may partner with Andy Hill CARE, DOH, community-based organizations, and other entities to increase the participation of persons who are members of underrepresented groups in clinical trials, including by asking Andy Hill CARE to create an outreach and engagement plan related to specific clinical trials and provide grants to community-based agencies to implement the outreach and engagement plan, subject to appropriations.

Underrepresented demographic groups in clinical trials means a community or demographic group that is more likely to be historically marginalized and less likely to be included, and research and clinical trials based on race, sex, sexual orientation, socioeconomic status, age, or geographic location.

Appropriation: None.

Fiscal Note: Available.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony on Second Substitute House Bill (Health & Long Term Care): *The committee recommended a different version of the bill than what was heard.* PRO: The way we recruit subjects and reimburse for participation in clinical trials hinders the capacity of people from marginalized communities to participate. We should look at the whole spectrum starting with how grants are awarded. Progress is being made but the negative history is clear and loud in communities that have been historically wronged. We need to start by building trust within marginalized communities, give them time, and use this opportunity as a foundation. When I was being treated for cervical cancer I was asked to participate in a clinical trial, but didn't trust it at first because of the history. My participation will help other women of color have safer therapies. Diverse participation will increase due to outreach. While we are heartened to see progress towards greater inclusivity, we are concerned and disappointed to see the funding go to large institutions instead of community organizations. Community organizations were at the forefront of the pandemic translating materials and providing culturally appropriate solutions, and their participation is needed for this legislation to succeed.

Persons Testifying (Health & Long Term Care): PRO: Representative My-Linh Thai, Prime Sponsor; Tamara Clough, American Cancer Society Cancer Action Network; Bryan Yambe, Pacific Islander Health Board of Washington.

Persons Signed In To Testify But Not Testifying (Health & Long Term Care): No one.

Staff Summary of Public Testimony on Bill as Amended by Health & Long Term Care (Ways & Means): *The committee recommended a different version of the bill than what was heard.* None.

Persons Testifying (Ways & Means): No one.

Persons Signed In To Testify But Not Testifying (Ways & Means): No one.