SENATE BILL REPORT
2SHB 1745

As of March 30, 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.

Brief Summary of Amended Bill

- Establishes a diversity in clinical trials program at the Washington State Institutional Review Board.
- Requires any entity 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 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

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

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.

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

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. WSRIB 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 may:

- collaborate with medical facilities, health authorities, nonprofit organizations, and scientific investigators and institutions to assist in recruiting persons who are members of underrepresented demographic groups to participate in clinical trials;
- establish a website to provide information concerning methods for identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials;
- provide links to entities performing research relating to drugs or medical devices in Washington;
- apply for grants to fund the diversity in clinical trials program; and
- submit a biannual report starting July 1, 2024, to the health care committees of the Legislature.

Any state entity that receives funding from the National Institutes of Health (NIH) to conduct clinical trials of drugs or medical devices 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 and provide translation services or bilingual staff for trial screening.

The factors considered by the Andy Hill Cancer Research Endowment 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.

Demographic groups underrepresented in clinical trials may include persons who are underrepresented by race, sex, sexual orientation, socioeconomic status, or age.

EFFECT OF HEALTH & LONG TERM CARE COMMITTEE AMENDMENT(S):

- Directs the Washington State Institutional Review Board to establish a Diversity in Clinical Trials Program with duties including providing assistance to research entities in identifying and recruiting members of underrepresented demographic groups to participate in clinical trials, to establish a website, and to consider publication of a biannual report.
- Requires any state entity which receives NIH funding for clinical trials of drugs or medical devices to adopt a policy concerning identification and recruitment of underrepresented demographic groups, to collaborate with community-based organizations, and to use methods to recruit members of underrepresented groups which are recognized by the United States Food and Drug Administration.
- Removes the requirement for entities which receive NIH funding for clinical trials of drugs or medical devices to provide for electronic consent when not prohibited by the granting entity or federal regulation.

Appropriation: None.

Fiscal Note: Available. New fiscal note requested on March 23, 2023.

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): None.

Persons Testifying (Ways & Means): No one.

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