

SENATE BILL REPORT

2SHB 1745

As of March 17, 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.

Brief Summary of Bill

- Requires any hospital or state entity that receives funding from the National Institutes of Health to take specified steps to increase the diversity of participants in clinical trials.
- Requires the Washington State Institutional Review Board and 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

Staff: Kevin Black (786-7747)

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

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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 Bill: Any hospital or state entity that receives funding from the National Institutes of Health to conduct clinical trials of drugs or medical devices, including the University of Washington and Washington State University, must:

- offer trial participants information in a language other than English;
- provide culturally specific recruitment materials alongside general enrollment materials; and
- provide electronic consent when not prohibited by the granting entity or federal

regulation.

The factors considered by the Andy Hill Cancer Research Endowment program and WSIRB 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.

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

Appropriation: The bill contains a null and void clause requiring specific funding be provided in an omnibus appropriation act.

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: 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: 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: No one.