HOUSE BILL REPORT
2SHB 1745

As Passed Legislature

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:

Committee Activity:

Health Care & Wellness: 2/14/23, 2/17/23 [DPS];
Appropriations: 2/23/23, 2/24/23 [DP2S(w/o sub HCW)].

Floor Activity:

Passed House: 3/6/23, 95-0.
Senate Amended.
Passed Senate: 4/12/23, 49-0.
House Concurred.
Passed House: 4/19/23, 98-0.
Passed Legislature.

Brief Summary of Second Substitute Bill

- Requires the Washington State Institutional Review Board (Review Board) to establish a diversity in clinical trials program.
- Requires the Department of Health (DOH), in consultation with others, to analyze and provide recommendations on matters related to increasing participation by underrepresented groups in clinical trials and provide a report to the Legislature.
- Authorizes the Andy Hill Cancer Research Endowment (Andy Hill Endowment), subject to appropriation, to provide grant funding to community-based organizations to provide outreach and engagement for specific clinical trials at the request of the University of Washington or

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.

Washington State University based on a community outreach and engagement plan developed by the requesting university, the Andy Hill Endowment, the DOH, and community-based organizations.

- Requires any state entity or hospital that receives National Institutes of Health funding for drug and medical device clinical trials to adopt a policy concerning identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials, offer information in languages other than English, provide translation services or bilingual staff, provide culturally specific recruitment materials, and provide electronic consent when available.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 17 members: Representatives Riccelli, Chair; Bateman, Vice Chair; Schmick, Ranking Minority Member; Hutchins, Assistant Ranking Minority Member; Barnard, Bronoske, Davis, Graham, Harris, Macri, Maycumber, Mosbrucker, Orwall, Simmons, Stonier, Thai and Tharinger.

Staff: Kim Weidenaar (786-7120).

HOUSE COMMITTEE ON APPROPRIATIONS

Majority Report: The second substitute bill be substituted therefor and the second substitute bill do pass and do not pass the substitute bill by Committee on Health Care & Wellness. Signed by 30 members: Representatives Ormsby, Chair; Bergquist, Vice Chair; Gregerson, Vice Chair; Macri, Vice Chair; Stokesbary, Ranking Minority Member; Chambers, Assistant Ranking Minority Member; Corry, Assistant Ranking Minority Member; Berg, Chandler, Chopp, Connors, Couture, Davis, Dye, Fitzgibbon, Harris, Lekanoff, Pollet, Riccelli, Rude, Ryu, Sandlin, Schmick, Senn, Simmons, Slatter, Springer, Steele, Stonier and Tharinger.

Staff: Kate Henry (786-7349).

Background:

Institutional Review Boards.
An Institutional Review Board (IRB) is a formally designated group that reviews and monitors research involving human subjects. Research that involves human subjects must receive IRB approval. An IRB is responsible for reviewing research protocols and related materials to ensure protection of the rights and welfare of human subjects in research and

may approve, require modifications, or disapprove research.

Washington State Institutional Review Board.
The Washington State Institutional Review Board (Review Board) is a designated IRB for a number of different Washington state agencies, including the Department of Children, Youth, and Families; Department of Health, Department of Corrections, Department of Social and Health Services, Health Care Authority, Department of Labor and Industries, and the Office of Financial Management. The Review Board also serves as a designated IRB for other local and state agencies. The Review Board is responsible for providing the requisite regulatory review, approval and oversight of research that may involve these state agencies' clients, beneficiaries, patients, wards and state agency employees or these individuals' state agency personal records, in order to ensure the protection of the rights and welfare of human subjects in research.

Andy Hill Cancer Research Endowment.
The Andy Hill Cancer Research Endowment (Andy Hill Endowment), also known as the Andy Hill CARE Fund, makes grants to public and private entities for the promotion of cancer research. The Andy Hill Endowment evaluates requests for funding 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 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.

Summary of Second Substitute Bill:

The Washington State Institutional Review Board (Review Board) for state agencies is codified and defined as the review board established pursuant to 45 C.F.R. Part 46, as the designated Institutional Review Board for the Department of Social and Health Services, the Department of Health (DOH), the Department of Labor and Industries, and other state agencies.

The Review Board 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. The Review Board must compile and share information and resources in an accessible fashion to assist entities in Washington that conduct clinical trials with increasing diversity of participation, including:

- information on 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 these efforts; and
- links to websites maintained by medical facilities, health authorities, local governmental entities, nonprofit organizations, and scientific investigators and institutions that are performing research related to drugs or medical devices in Washington.

Any state entity or hospital that receives funding from the National Institutes of Health 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 that requires investigators to collaborate with community-based organizations and to use methods recognized by the United States Food and Drug Administration to identify and recruit persons who are members of underrepresented demographic groups;
- provide trial participants information in languages other than English;
- provide translation services or bilingual staff for trial screening;
- provide culturally specific recruitment materials; and
- provide electronic consent when not prohibited by the granting entity or federal regulations.

The Andy Hill Cancer Research Endowment (Andy Hill Endowment) must evaluate requests based on the following factors in addition to the current considerations:

- 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 for drugs and medical devices.

The DOH, in consultation with UW, WSU, Andy Hill Endowment, Washington community health boards and initiatives, community-based organizations, and other relevant research organizations, must analyze and provide recommendations on the following by December 1, 2023:

- the demographic groups and populations that are currently represented and

underrepresented in clinical trials in Washington;
- barriers for persons who are members of underrepresented demographic groups to participate in clinical trials; and
- approaches for how clinical trials can successfully partner with community-based organizations to provide outreach.

Beginning January 1, 2024, the UW and WSU may partner with the Andy Hill Endowment, the DOH, community-based organizations, and other entities to increase the participation of persons who are members of underrepresented groups in a clinical trial. If an investigator at UW or WSU determines that a drug or medical device clinical trial would benefit from specific community outreach and engagement to increase participation of an underrepresented community, the university may request the assistance of DOH and the Andy Hill Endowment to create an outreach and engagement plan related to the specific clinical trials. Subject to the availability of appropriated funds, the Andy Hill Endowment may administer grants to Washington community-based organizations to implement the outreach plan and to provide meaningful and real-time community engagement with the goal of increasing the demographic group or community's participation in the clinical trial.

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

The sections related to the Review Board constitute a new chapter in Title 69.

Appropriation: None.

Fiscal Note: Available.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed. However, the bill is null and void unless funded in the budget.

Staff Summary of Public Testimony (Health Care & Wellness):

(In support) Clinical trials are the first step for developing new drugs for cancer and other conditions. Joining a medical trial is a complex problem and the lack of diversity in trials is problematic in several ways. It compounds access to treatment disparities, and it limits the understanding of the impacts of a drug or medical device across all populations.

Communities of color are diligently working to build and ensure trust between communities of color, the government, and research. This bill is an attempt to create a foundation of trust to bring in more trial participants. Many patients from communities of color do not trust clinical trials because of the history of research in this country. Without increasing the diversity in clinical trials and providing culturally appropriate education and outreach,

individuals from underrepresented communities will not have trust in the trials or know that they are safe. Individuals from communities of color need to participate in trials to help find treatments that will work for everyone no matter their color. This bill would be the first in that nation and it will connect more diverse patients with clinical trials.

It is important that all people have access to new and exciting treatments. Clinical trials have the opportunity to give early access to lifesaving medications. Many potential patients do not have access to clinical trials, and this is particularly true for communities of color. Participating in trials is also difficult and is often harder for people who are older or do not live in urban areas. There are many barriers to clinical trial participation and some are working currently to fund projects that address some of these barriers.

There should be more outreach for clinical trials and work to reach groups in a more accessible way, including materials for communities of color and the availability of materials in languages other than English. Biases should not stand in the way of health care, which is a right for all. Federal rules only require translation when the trial targets populations with limited English proficiency. The fiscal impact for large research institutions with a high number of new trials each year will be significant because the institution assumes that translation is needed for every trial.

This bill could be improved in three ways. First, the definition of underrepresented groups does not include people with restricted liberty. This population has been generally excluded from trials in the recent past. Second, the trials covered by this bill should be broader than just drugs and medical devices, which account for only 10 percent of all trials. Finally, the bill should be strengthened to require these things, unless the research can justify why they are excluding the population because it is either too onerous or unnecessary.

(Opposed) None.

Staff Summary of Public Testimony (Appropriations):

(In support) This bill is a top priority for patient groups. Diversity in clinical trials is key in the development of treatments and medicines to acknowledge how treatments impact people differently. The quality of research can improve when understanding how trials impact different populations.

The research institutions are working on getting more people to participate in clinical trials. Federal regulations currently require institutions to provide outreach for participation in trials that target certain participants for specific research; the bill requires outreach for all clinical trials. The outreach and translation services cost money. An amendment is being worked on to address concerns and achieve a common goal to increase diversity in clinical trials.

(Opposed) None.

Persons Testifying (Health Care & Wellness): Representative My-Linh Thai, prime sponsor; Lyset Cadena, Andy Hill Cancer Research Endowment Fund; Adam Zarrin, Leukemia and Lymphoma Society; Yvette Mercer; Carol Coram and Tamara Clough, American Cancer Society Cancer Action Network; Marc Stern; Gordon Tupulua, Pacific Islander Health Board; Andrew Cowan, Fred Hutchinson Cancer Center; Connor Haggerty, Washington State University; and Ian Goodhew, University of Washington Medicine.

Persons Testifying (Appropriations): Erin Dziedzic, Leukemia and Lymphoma Society; and Ian Goodhew, University of Washington Medicine.

Persons Signed In To Testify But Not Testifying (Health Care & Wellness): None.

Persons Signed In To Testify But Not Testifying (Appropriations): None.