HOUSE BILL REPORT
HB 1745

As Reported by House Committee On:
Health Care & Wellness
Appropriations

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

Brief Description: Improving diversity in clinical trials.

Sponsors: 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)].

Brief Summary of Second Substitute Bill

- Requires the University of Washington, Washington State University, and any hospital or state agency that receives National Institutes of Health funding for drug and medical device clinical trials to offer information in a language other than English, to provide culturally specific recruitment materials, and to provide electronic consent when available.
- Codifies the Washington State Institutional Review Board (Review Board).
- Requires the Review Board and the Andy Hill Cancer Research Endowment to consider in their evaluation four factors related to increasing participation of underrepresented communities in clinical trials of drugs and medical devices.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

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: 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).

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 (Endowment), also known as the Andy Hill CARE Fund, makes grants to public and private entities for the promotion of cancer research. The 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 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 Substitute Bill:

The Andy Hill Cancer Research Endowment (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 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, the Department of Labor and Industries, and other state agencies. Any submissions or proposals submitted to the Review Board must include the same four items the Endowment must evaluate above, which the Review Board must consider.

The University of Washington, Washington State University, and any state agency or hospital that receives funding from the National Institutes of Health to conduct clinical trials of drugs or medical devices must adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials of drugs and medical devices. The policy must include requirements to:

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

"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.

Substitute Bill Compared to Original Bill:

The substitute bill:

- modifies the provisions related to the ability to provide electronic consent, by limiting this consideration or requirement to when it is not prohibited by the granting entity or federal regulations; and
- specifies that the requirements and considerations only apply to clinical trials of drugs or medical devices.

Appropriation: None.

Fiscal Note: Preliminary fiscal note available. New fiscal note requested on February 19, 2023.

Effective Date of Substitute Bill: The bill takes effect 90 days after adjournment of the session in which the bill is passed.

Staff Summary of Public Testimony:

(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.

Persons Testifying: 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 Signed In To Testify But Not Testifying: None.

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).

Summary of Recommendation of Committee On Appropriations Compared to Recommendation of Committee On Health Care & Wellness:

As compared to the substitute bill, the second substitute bill:

- replaces the requirement for the University of Washington, Washington State

University, and any hospital or state agency that receives National Institutes of Health funding for drug and medical device clinical trials (entities) to adopt a policy that includes requirements to offer trial participants information in a language other than English, to provide culturally specific recruitment materials, and to provide electronic consent when not prohibited by the granting entity or federal regulation with a requirement to provide these services and options;
- removes the requirement for entities to provide other strategies of outreach and engagement to increase participation of underrepresented communities in clinical trials of drugs and medical devices; and
- adds a null and void clause, making the act null and void if specific funding is not provided by June 30, 2023, in the omnibus appropriations act.

Appropriation: None.

Fiscal Note: Available.

Effective Date of Second Substitute Bill: 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:

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

Persons Signed In To Testify But Not Testifying: None.