HOUSE BILL REPORT
SSB 5388

As Reported by House Committee On:
Health Care & Wellness

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

Brief Description: Concerning improving diversity in clinical trials.

Sponsors: Senate Committee on Health & Long Term Care (originally sponsored by Senators Rivers, Cleveland, Muzzall, Conway, Frame, Hasegawa, Keiser, Lovelett, Lovick, Pedersen, Rolfes, Saldaña, Valdez and Wilson, C.).

Brief History:
Committee Activity:
Health Care & Wellness: 3/17/23, 3/29/23 [DPA].

Brief Summary of Substitute Bill
(As Amended By Committee)

- 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.
- Requires the Department of Health, in consultation with research and community-based entities, to study and provide recommendations on increasing access to clinical trials and participation in clinical trials by

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persons who are members of underrepresented communities.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: Do pass as amended. Signed by 11 members: Representatives Riccelli, Chair; Bateman, Vice Chair; Bronoske, Davis, Macri, Maycumber, Orwall, Simmons, Stonier, Thai and Tharinger.

Minority Report: Do not pass. Signed by 3 members: Representatives Schmick, Ranking Minority Member; Graham and Harris.

Minority Report: Without recommendation. Signed by 3 members: Representatives Hutchins, Assistant Ranking Minority Member; Barnard and Mosbrucker.

Staff: Kim Weidenaar (786-7120).

Background:

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

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 and the 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 housed within the Department of Social and Health Services (DSHS) and is the designated IRB for a number of Washington state agencies, including the Department of Children, Youth, and Families; Department of Health; Department of Corrections; DSHS; 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.

Summary of Amended 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 (UW), Washington State University (WSU), 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.

The Department of Health (DOH) in consultation with the UW, the WSU, the Endowment, Washington community health boards and initiatives, community-based organizations, and other relevant research organizations, must analyze and provide recommendations on the following:

- what demographic groups and populations are currently represented and underrepresented in clinical trials in Washington, including geographic representation;
- information concerning methods for identifying and recruiting persons who are

members of underrepresented demographic groups to participate in clinical trials;
- barriers for persons who are members of underrepresented demographic groups to participate in clinical trials in Washington, including barriers related to transportation;
- approaches for how clinical trials can successfully provide outreach to underrepresented communities and recommendations on what clinical trials should provide or consider to increase participation in clinical trials; and
- a list of appropriate entities that may be able to provide assistance with efforts to increase participation by underrepresented demographic groups in clinical trials.

By December 1, 2023, the DOH must report to the Legislature the results of the analysis and recommendations to increase diversity and reduce barriers for participants in clinical trials.

"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.

Amended Bill Compared to Substitute Bill:

The amended bill:
- removes the underlying provisions of the bill;
- codifies the Washington State Institutional Review Board (Review Board);
- requires the Andy Hill Cancer Research Endowment (Endowment) and the Review Board to evaluate requests and submissions 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, if not prohibited by the grantor or federal regulations; and
    - other evidence of outreach and engagement to increase participation of underrepresented communities in clinical trials for drugs and medical devices;
- requires 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 to adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials for 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, if not prohibited by the grantor or federal

regulations; and
    - provide other strategies of outreach and engagement to increase participation of underrepresented communities;
- requires the Department of Health in consultation with a number of research and community-based entities to study and provide recommendations for increasing access to clinical trials and participation in clinical trials by persons who are members of underrepresented communities; and
- provides intent language.

Appropriation: None.

Fiscal Note: Available.

Effective Date of Amended 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) This bill started as an adventure to see why some demographics are not seeing the success with pharmaceuticals that other groups are. During the process it became apparent that certain groups are underrepresented in clinical trials. Every health journal includes articles about the disparate impacts of health conditions on certain demographics. If a drug has not been tested in these groups, we do not know that it will work. This bill gives people the best shot at survival and there is a lot of excitement with this bill.

Lifesaving advances must be appropriate for and available to everyone. Certain demographic groups are more susceptible to certain cancers or do not respond to certain treatments the same way as others. Black women are more likely to have triple negative breast cancer and to be diagnosed at a younger age compared to other demographic groups.

It is vital that we have diversity in clinical trials. Chadwick Boseman had incredibly aggressive colon cancer, which is more common for Black individuals, and by the time he found out about the cancer he had nearly passed away. It is more than time for individuals of color to be a part of trials and to get the opportunity to live long and full lives.

(Opposed) None.

Persons Testifying: Senator Ann Rivers, prime sponsor; Kirsten Smith, Susan G. Komen; and Chyna Lockhart, Bleeding Disorder Foundation of Washington.

Persons Signed In To Testify But Not Testifying: None.