Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

SSB 5723

Brief Description: Concerning improving diversity in clinical trials.

Sponsors: Senate Committee on Health & Long Term Care (originally sponsored by Senators Rivers, Keiser and Lovick).

Brief Summary of Substitute Bill

- Directs the Washington State Review Board to establish a program to encourage diversity in clinical trials for drugs and medical devices for underrepresented demographic groups.
- Requires state entities conducting clinical trials of drugs or medical devices to adopt policies for identifying and recruiting members of underrepresented demographic groups to participate in clinical trials.

Hearing Date: 2/21/22

Staff: Christopher Blake (786-7392).

Background:

Institutional Review Boards.
Institutional review boards are federally regulated entities that review research proposals to assure that the rights and welfare of human subjects are protected, risks to human subjects are minimized and not unreasonable in relation to the anticipated benefits, and the proposed study design and methods are appropriate.

The Washington State Institutional Review Board (Board) is the designated institutional review board for several state agencies, including the Department of Social and Health Services, the Department of Health, the Health Care Authority, and the Department of Labor and Industries.

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.

The Board consists of members who are representatives of several state agencies, as well others who are not affiliated with any state agency. The Department of Social and Health Services provides support to the Board. The Board is responsible for providing regulatory review, approval, and oversight of research that involves the covered state agencies' clients, beneficiaries, patients, wards, and agency employees, including their personal records. The Board must ensure the protection of human research subjects and maintain guidelines that meet federal standards and address topics including review and certification requirements, approval and disapproval authority, qualifications of investigators, informed consent requirements, and publication conditions.

Diversity in Clinical Trials.
In 2016 the federal Food and Drug Administration released guidance for the collection of race and ethnicity data in clinical trials. The guidance addresses ways to achieve more consistent demographic subgroup data collection by establishing minimum standards for maintaining, collecting, and presenting data on race and ethnicity.

Summary of Bill:

The Washington State Review Board (Board) must establish a program to encourage diversity in clinical trials for drugs and medical devices. The program must encourage participation in clinical trials by persons in demographic groups that are underrepresented in clinical trials, including by race, sex, sexual orientation, socioeconomic status, and age. To develop the program the Board may:

- review the most recent version of "Collection of Race and Ethnicity Data in Clinical Trials - Guidance for Industry and Food and Drug Administration Staff," published by the federal Food and Drug Administration;
- collaborate with entities performing drug or medical device clinical trials to assist them in the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials;
- establish a website with information about strategies to identify and recruit members of underrepresented demographic groups to participate in clinical trials, including links to entities in Washington that are performing research related to drugs or medical devices; and
- apply for grants to fund the program.

Beginning July 1, 2023, the Board must submit a report to the health care committees of the Legislature regarding the status and results of the program.

State entities that conduct clinical trials of drugs or medical devices, including the University of Washington, must adopt a policy that includes evidence-based strategies to identify and recruit representative samples of members of underrepresented demographic groups to participate in clinical trials. The policy must require that researchers conducting clinical trials collaborate with and provide resources and funding to community-based organizations serving underrepresented communities.

It is declared that the policy of the state is to: (1) improve the completeness and quality of data concerning diverse demographic groups in clinical trials; (2) identify barriers for demographic groups that are underrepresented in clinical trials and use evidence-based strategies to encourage greater participation; and (3) make underrepresented demographic group data more available and transparent.

Appropriation: None.

Fiscal Note: Preliminary fiscal note available.

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