SENATE BILL REPORT
SB 5723

As of January 19, 2022

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

Brief Description: Concerning improving diversity in clinical trials.

Sponsors: Senators Rivers, Keiser and Lovick.

Brief History:
Committee Activity: Health & Long Term Care: 1/19/22.

Brief Summary of Bill

- Requires the Washington State Institutional Review Board to establish a diversity in clinical trials program.
- Requires state entities that conduct clinical trials for drugs or medical devices to adopt a policy for identifying and recruiting participants from underrepresented demographic groups.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: LeighBeth Merrick (786-7445)

Background: The Washington State Institutional Review Board (WSIRB) is a designated institutional review board for a number of Washington State agencies and research institutions. Research under the jurisdiction of the Department of Social and Health Services, the Department of Health, and the Department of Labor and Industries cannot begin until the WSIRB approves the proposed research protocols. The WSIRB must ensure the rights and welfare of individuals who participate in research are protected; that the risks to individuals are minimized, are not unreasonable, and are outweighed by the potential benefits to the individual or by the knowledge to be gained; and that the proposed research design and methods are adequate in light of the stated research objectives.

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.

Clinical trials are research studies that explore whether a medical strategy, treatment, or device is safe and effective for humans. Governmental organizations; academic or research institutions; or pharmaceutical, medical device, or biotechnology companies may undertake a clinical trial. The United States Food and Drug Administration (FDA) regulates the conduct of clinical trials.

Summary of Bill: The WSIRB is required to establish a diversity in clinical trails program. The goal of the program is to encourage more participation from underrepresented demographic groups in clinical trials of drugs and medical devices. Demographic groups that may be underrepresented include race, sex, sexual orientation, socioeconomic status, and age. When developing the program, the WSIRB may:

- review the most recent version of the *Collection of Race and Ethnicity Data in Clinical Trials - Guidance for Industry and Food and Drug Administration Staff;*
- collaborate with entities that are performing drug or medical device clinical trials;
- establish and maintain a website that provides methods for achieving the program's goal, and inventories all of the medical device or drug research that is being conducted in Washington State;
- apply for grants from any source to fund the program; and
- beginning July 1, 2023, and every odd-numbered year thereafter, submit status reports to the health care committees of the Legislature.

State entities, including the University of Washington, that conduct clinical trials of drugs or medical devices must adopt a policy for identifying and recruiting participants from underrepresented demographic groups. The policy must require collaboration with community-based organizations, and use methods recognized by the FDA.

Appropriation: None.

Fiscal Note: Requested on January 10, 2022.

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: This is a simple bill that helps include underrepresented communities in clinical trials to make sure all people that have a treatment prescribed to them will benefit. Diversity in clinical trials is important and necessary to determine how age, race and gender impacts an individual's ability to metabolize a drug. Lives are put in danger when these factors aren't considered in clinical trials. We request including a provision to ensure all patients that participate in clinical trials are well-informed before they enroll.

Persons Testifying: PRO: Senator Ann Rivers, Prime Sponsor; REX JOHNSON,

Washington Advocates for Patient Safety; Ron Muzzall, Senator.

Persons Signed In To Testify But Not Testifying: No one.