SENATE BILL REPORT
SB 5388

As of February 2, 2023

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

Brief Description: Concerning improving diversity in clinical trials.

Sponsors: Senators Rivers, Cleveland, Muzzall, Conway, Frame, Hasegawa, Keiser, Lovelett, Lovick, Pedersen, Rolfes, Saldaña, Valdez and Wilson, C..

Brief History:
Committee Activity: Health & Long Term Care: 2/03/23.

Brief Summary of Bill

- Establishes a diversity in clinical trials program at the Washington State Institutional Review Board.
- Requires any entity receiving funding from the National Institutes of Health to conduct clinical trials of drugs or medical devices to adopt a policy concerning recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials.
- Requires investigators in clinical trials to collaborate with community-based organizations.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: Kevin Black (786-7747)

Background: The Washington State Institutional Review Board. An institutional review board is a federally-mandated entity that reviews research proposals to assure that the rights and welfare of human subjects are protected, risks to human subjects are minimized and not unreasonable, and that proposed study designs and methods are appropriate.

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 Washington State Institutional Review Board (WSIRB) is the designated institutional review board for several state agencies, including the Department of Social and Health Services, Department of Health, Health Care Authority, and Department of Labor and Industries. WSIRB provides regulatory review, approval, and oversight of research that involves state agency clients, beneficiaries, patients, wards, and employees. WSRIB ensures the protection of human research subjects and maintains guidelines addressing various topics related to clinical trials.

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

Summary of Bill: WSIRB 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. WSIRB may:

- collaborate with medical facilities, health authorities, nonprofit organizations, and scientific investigators and institutions to assist in recruiting persons who are members of underrepresented demographic groups to participate in clinical trials;
- establish a website to provide information concerning methods for identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials;
- provide links to entities performing research relating to drugs or medical devices in Washington;
- apply for grants to fund the diversity in clinical trials program; and
- submit a biannual report starting July 1, 2024, to the health care committees of the Legislature.

Any state entity that receives funding from the National Institutes of Health to conduct clinical trials of drugs or medical devices must adopt a policy concerning identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials. Investigators conducting clinical trials must collaborate with community-based organizations and use methods to recruit persons who are members of underrepresented demographic groups to participate in clinical trials recognized by the United States Food and Drug Administration.

Demographic groups underrepresented in clinical trials may include persons who are underrepresented by race, sex, sexual orientation, socioeconomic status, or age.

Appropriation: None.

Fiscal Note: Requested on January 23, 2023.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.