Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

SSB 5388

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 Summary of Substitute Bill

- Requires the Washington State Institutional Review Board to establish a diversity in clinical trials program.
- Requires any state entity receiving funding from the National Institutes of Health to conduct clinical trials of drugs or medical devices to adopt a policy to identify and recruit persons who are members of underrepresented demographic groups.

Hearing Date: 3/17/23

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.

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.

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 Bill:

The Washington State Institutional Review Board (Review Board) must establish a diversity in clinical trials program (program) to encourage participation in clinical trials of drugs and medical devices by persons who are members of demographic groups that are underrepresented in clinical trials. In developing the program, the Review 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 (FDA) Staff;"
- collaborate with entities and individuals that are performing research relating to drugs or medical devices to assist with identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials;
- establish and maintain a website that: provides methods recognized by the FDA for identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials and contains links to websites maintained by other entities performing research relating to drugs or medical devices in Washington;
- apply for grants to fund the program; and
- submit a biennial report on the status and results of the diversity in clinical trials program 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 to identify and recruit persons who are members of underrepresented demographic groups to participate in clinical trials. The policy must include requirements that investigators collaborate with community-based organizations and use methods recognized by the FDA;
- provide information to trial participants in languages other than English; and

- provide translation services or bilingual staff for trial screening.

Demographic groups that are underrepresented in clinical trials may include persons who are underrepresented by race, sex, sexual orientation, socioeconomic status, and age. A new chapter in Title 69 RCW is created.

Appropriation: None.

Fiscal Note: Available.

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