Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

HB 2304

Brief Description: Concerning improving diversity in clinical trials.

Sponsors: Representative Lovick.

Brief Summary of 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 that conduct 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: 1/9/18

Staff: Chris Blake (786-7392).

Background:

Institutional Review Boards.

Institutional review boards are federally-regulated entities that review research proposals to assure that risks to subjects are minimized, risks to subjects are reasonable in relation to the anticipated benefits, selection of subjects is equitable, and informed consent requirements and procedures are met.

The Department of Social and Health Services (Department) supports the Washington State Institutional Review Board (Board). Through interagency agreements, the Department of Health, Department of Labor and Industries, and other state agencies use the Board to review human subjects research that they conduct. The Board consists of about 14 to 16 full members who are representatives of several state agencies as well others who are not affiliated with any state agency. The Board is authorized to review and approve research in each agency's

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jurisdiction; prescribe specific scientific and ethical restrictions or conditions on research projects to ensure acceptable conduct of the project and the protection of human subjects; and suspend or terminate research projects that are not in compliance with Board requirements or that have been associated with unexpected harm to participants.

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 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:

- use the published guidance from the federal Food and Drug Administration (FDA) titled "Collection of Race and Ethnicity Data in Clinical Trials - Guidance for Industry and FDAStaff;"
- assist scientific investigators in the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials by collaborating with stakeholders, including medical facilities, health authorities, local government entities, nonprofit organizations, and scientific investigators and institutions;
- establish a web site with information about methods for identifying and recruiting 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;
- apply for grants to fund the program; and
- submit reports every two years, beginning July 1, 2019.

State entities that conduct clinical trials of drugs or medical devices, including the University of Washington, must adopt policies for identifying and recruiting members of underrepresented demographic groups to participate in clinical trials. The policies must require that investigators use federally-recognized methods for identifying and recruiting members of underrepresented demographic groups to participate in their drug trials.

Legislative findings are made regarding the poor representation of ethnic and racial groups in clinical trials for new medical products. The policy of the state is declared to be improving the completeness and quality of data concerning diverse demographic groups in clinical trials; identifing barriers for demographic groups that are underrepresented in clinical trials and use federally-recognized strategies to encourage greater participation; and making demographic group data more available and transparent.

Appropriation: None.

Fiscal Note: Requested on January 3, 2018.

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