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**SUBSTITUTE SENATE BILL 5723**

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**State of Washington**

**67th Legislature**

**2022 Regular Session**

**By** Senate Health & Long Term Care (originally sponsored by Senators Rivers, Keiser, and Lovick)

READ FIRST TIME 01/31/22.

1 AN ACT Relating to improving diversity in clinical trials; and  
2 adding a new chapter to Title 69 RCW.

3 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

4 NEW SECTION. **Sec. 1.** (1) The legislature finds that controlled  
5 clinical trials provide a critical base of evidence for evaluating  
6 whether a medical product is effective before the product is approved  
7 for marketing. The food and drug administration has evaluated  
8 demographic profiles of people participating in clinical trials for  
9 approved drugs and found that some groups, especially ethnic and  
10 racial groups, aren't always well represented in clinical trials.  
11 Diversity in clinical trials is necessary to effectively determine  
12 how race, gender, and age impacts how a person metabolizes a drug.

13 (2) Therefore, it is the policy of the state to:

14 (a) Improve the representativeness and quality of data concerning  
15 diverse demographic groups that is collected, reported, and analyzed  
16 for the purposes of clinical trials of drugs and medical devices;

17 (b) Identify barriers to participation in clinical trials by  
18 persons who are members of demographic groups that are  
19 underrepresented in such trials and employ evidence-based strategies  
20 to encourage greater participation and achieve a representative  
21 sampling in clinical trials by such population groups; and

1 (c) Make data concerning underrepresented demographic groups that  
2 is collected, reported, and analyzed for the purposes of clinical  
3 trials more available and transparent.

4 NEW SECTION. **Sec. 2.** The definitions in this section apply  
5 throughout this chapter unless the context clearly requires  
6 otherwise.

7 "Washington state review board" or "review board" means the  
8 Washington state institutional review board, established pursuant to  
9 45 C.F.R. Part 46, which is the designated institutional review board  
10 for the department of social and health services, the department of  
11 health, the department of labor and industries, and other state  
12 agencies.

13 NEW SECTION. **Sec. 3.** (1) The Washington state review board must  
14 establish a diversity in clinical trials program to encourage  
15 participation in clinical trials of drugs and medical devices by  
16 persons who are members of demographic groups that are  
17 underrepresented in clinical trials. In developing this program, the  
18 review board may:

19 (a) Review the most recent version of "Collection of Race and  
20 Ethnicity Data in Clinical Trials — Guidance for Industry and Food  
21 and Drug Administration Staff," published by the United States food  
22 and drug administration;

23 (b) Collaborate with medical facilities, health authorities, and  
24 other local governmental entities, nonprofit organizations, and  
25 scientific investigators and institutions that are performing  
26 research relating to drugs or medical devices to assist such  
27 investigators and institutions in identifying and recruiting persons  
28 who are members of underrepresented demographic groups to participate  
29 in clinical trials;

30 (c) Establish and maintain a website that:

31 (i) Provides information concerning evidence-based strategies for  
32 identifying and recruiting persons who are members of  
33 underrepresented demographic groups to participate in clinical  
34 trials; and

35 (ii) Contains links to websites maintained by medical facilities,  
36 health authorities, and other local governmental entities, nonprofit  
37 organizations, and scientific investigators and institutions that are

1 performing research relating to drugs or medical devices in this  
2 state;

3 (d) Apply for grants from any source, including, without  
4 limitation, the federal government, to fund the diversity in clinical  
5 trials program; and

6 (e) Beginning July 1, 2023, and every odd-numbered year  
7 thereafter, submit a report concerning the status and results of the  
8 diversity in clinical trials program to the health care committees of  
9 the legislature.

10 (2) State entities that conduct clinical trials of drugs or  
11 medical devices, including the University of Washington, must adopt a  
12 policy concerning the identification and recruitment of  
13 representative samples of persons who are members of underrepresented  
14 demographic groups to participate in clinical trials. This policy  
15 must include requirements that investigators who are conducting  
16 clinical trials collaborate with and provide resources and funding to  
17 community-based organizations serving such communities and use  
18 evidence-based strategies to identify and recruit such persons to  
19 participate in those clinical trials.

20 (3) For the purposes of this section, demographic groups that are  
21 underrepresented in clinical trials may include persons who are  
22 underrepresented by race, sex, sexual orientation, socioeconomic  
23 status, and age.

24 NEW SECTION. **Sec. 4.** Sections 1 through 3 of this act  
25 constitute a new chapter in Title 69 RCW.

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