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**SENATE BILL 5723**

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**State of Washington**

**67th Legislature**

**2022 Regular Session**

**By** Senators Rivers, Keiser, and Lovick

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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 completeness 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 strategies recognized by  
20 the United States food and drug administration to encourage greater  
21 participation in clinical trials by such persons; and

1 (c) Make data concerning demographic groups that is collected,  
2 reported, and analyzed for the purposes of clinical trials more  
3 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 methods recognized by the  
32 United States food and drug administration for identifying and  
33 recruiting persons who are members of underrepresented demographic  
34 groups to participate in clinical 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 persons who  
13 are members of underrepresented demographic groups to participate in  
14 clinical trials. This policy must include requirements that  
15 investigators who are conducting clinical trials collaborate with  
16 community-based organizations and use methods recognized by the  
17 United States food and drug administration to identify and recruit  
18 such persons to participate in those clinical trials.

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

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

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