
SUBSTITUTE SENATE BILL 5388

State of Washington

68th Legislature

2023 Regular Session

By Senate Health & Long Term Care (originally sponsored by Senators Rivers, Cleveland, Muzzall, Conway, Frame, Hasegawa, Keiser, Lovelett, Lovick, Pedersen, Rolfes, Saldaña, Valdez, and C. Wilson)

READ FIRST TIME 02/10/23.

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, are not 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, 2024, and every even-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) Any state entity that receives funding from the national
11 institutes of health to conduct clinical trials of drugs or medical
12 devices must:

13 (a) Adopt a policy concerning the identification and recruitment
14 of persons who are members of underrepresented demographic groups to
15 participate in clinical trials. This policy must include requirements
16 that investigators who are conducting clinical trials collaborate
17 with community-based organizations and use methods recognized by the
18 United States food and drug administration to identify and recruit
19 such persons to participate in those clinical trials;

20 (b) Provide information to trial participants in languages other
21 than English; and

22 (c) Provide translation services or bilingual staff for trial
23 screening.

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

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

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