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**SUBSTITUTE HOUSE BILL 1745**

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**State of Washington**

**68th Legislature**

**2023 Regular Session**

**By** House Health Care & Wellness (originally sponsored by Representatives Thai, Duerr, Doglio, Ormsby, and Macri)

READ FIRST TIME 02/17/23.

1 AN ACT Relating to improving diversity in clinical trials;  
2 amending RCW 43.348.040; reenacting and amending RCW 43.348.010;  
3 adding a new section to chapter 28B.20 RCW; adding a new section to  
4 chapter 28B.30 RCW; adding a new section to chapter 70.41 RCW; and  
5 adding a new chapter to Title 69 RCW.

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

7 **Sec. 1.** RCW 43.348.010 and 2018 c 4 s 1 are each reenacted and  
8 amended to read as follows:

9 The definitions in this section apply throughout this chapter  
10 unless the context clearly requires otherwise.

11 (1) "Board" means the governing board of the endowment.

12 (2) "Cancer" means a group of diseases involving unregulated cell  
13 growth.

14 (3) "Cancer patient advocacy organizations" means groups with  
15 offices in the state that promote cancer prevention and advocate on  
16 behalf of cancer patients.

17 (4) "Cancer research" means advanced and applied research and  
18 development relating to the causes, prevention, and diagnosis of  
19 cancer and care of cancer patients including the development of  
20 tests, genetic analysis, medications, processes, services, and  
21 technologies to optimize cancer therapies and their manufacture and

1 commercialization and includes the costs of recruiting scientists and  
2 establishing and equipping research facilities.

3 (5) "Commercial entity" means a for-profit entity located in the  
4 state that develops, manufactures, or sells goods or services  
5 relating to cancer prevention or care.

6 (6) "Committee" means an independent expert scientific review and  
7 advisory committee established under RCW 43.348.050.

8 (7) "Contribution agreement" means any agreement authorized under  
9 this chapter in which a private entity or a public entity other than  
10 the state agrees to provide to the endowment contributions for the  
11 purpose of cancer research, prevention, or care.

12 (8) "Costs" means the costs and expenses associated with the  
13 conduct of research, prevention, and care including, but not limited  
14 to, the cost of recruiting and compensating personnel, securing and  
15 financing facilities and equipment, and conducting clinical trials.

16 (9) "Department" means the department of commerce.

17 (10) "Endowment" means the Andy Hill cancer research endowment.

18 (11) "Fund" means the Andy Hill cancer research fund created in  
19 RCW 43.348.060(1)(b).

20 (12) "Health care delivery system" means hospitals and clinics  
21 providing care to patients in the state.

22 (13) "Life sciences research" means advanced and applied research  
23 and development intended to improve human health, including  
24 scientific study of the developing brain and human learning and  
25 development, and other areas of scientific research and development  
26 vital to the state's economy.

27 (14) "Prevention" means measures to prevent the development and  
28 progression of cancer, including education, vaccinations, and  
29 screening processes and technologies, and to reduce the risk of  
30 cancer.

31 (15) "Program" means the Andy Hill cancer research endowment  
32 program created in RCW 43.348.040.

33 (16) "Program administrator" means a private nonprofit  
34 corporation qualified as a tax-exempt entity under 26 U.S.C. Sec.  
35 501(c)(3) of the federal internal revenue code, with expertise in  
36 conducting or managing research granting activities, funds, or  
37 organizations.

38 (17) "Underrepresented community" or "underrepresented  
39 demographic group" means a community or demographic group that is  
40 more likely to be historically marginalized and less likely to be

1 included in research and clinical trials represented by race, sex,  
2 sexual orientation, socioeconomic status, age, and geographic  
3 location.

4 **Sec. 2.** RCW 43.348.040 and 2018 c 4 s 4 are each amended to read  
5 as follows:

6 (1) The Andy Hill cancer research endowment program is created.  
7 The purpose of the program is to make grants to public and private  
8 entities, including commercial entities, to fund or reimburse the  
9 entities pursuant to agreement for the promotion of cancer research  
10 to be conducted in the state. The endowment is to oversee and guide  
11 the program, including the solicitation, selection, and award of  
12 grants.

13 (2) The board must develop a plan for the allocation of projected  
14 amounts in the fund, which it must update annually, following at  
15 least one annual public hearing. The plan must provide for  
16 appropriate funding continuity and take into account the projected  
17 speed at which revenues will be available and amounts that can be  
18 spent during the plan period.

19 (3) The endowment must solicit requests for grant funding and  
20 evaluate the requests by reference to factors such as: (a) The  
21 quality of the proposed research or program; (b) its potential to  
22 improve health outcomes of persons with cancer, with particular  
23 attention to the likelihood that it will also lower health care  
24 costs, substitute for a more costly diagnostic or treatment modality,  
25 or offer a breakthrough treatment for a particular cancer or cancer-  
26 related condition or disease; (c) its potential for leveraging  
27 additional funding; (d) its potential to provide additional health  
28 care benefits or benefit other human diseases or conditions; (e) its  
29 potential to stimulate life science, health care, and biomedical  
30 employment in the state; (f) the geographic diversity of the grantees  
31 within Washington; (g) evidence of potential royalty, sales, or  
32 licensing revenue, or other commercialization-related revenue and  
33 contractual means to recapture such income for purposes of this  
34 chapter; ~~((and))~~ (h) evidence of public and private collaboration;  
35 (i) the ability to offer trial participants information in a language  
36 other than English; (j) the ability to provide culturally specific  
37 recruitment materials alongside general enrollment materials; (k) the  
38 ability to provide electronic consent when not prohibited by other  
39 granting entities or federal regulations; and (l) other evidence of

1 outreach and engagement to increase participation of underrepresented  
2 communities in clinical trials of drugs and medical devices.

3 (4) The endowment may not award a grant for a proposal that was  
4 not recommended by an independent expert scientific review and  
5 advisory committee under RCW 43.348.050.

6 (5) The endowment must issue an annual report to the public that  
7 sets forth its activities with respect to the fund, including grants  
8 awarded, grant-funded work in progress, research accomplishments,  
9 prevention, and care activities, and future program directions with  
10 respect to cancer research, prevention, and care. Each annual report  
11 regarding activities of the program and fund must include, but not be  
12 limited to, the following: The number and dollar amounts of grants;  
13 the grantees for the prior year; the endowment's administrative  
14 expenses; an assessment of the availability of funding for cancer  
15 research, prevention, and care from sources other than the endowment;  
16 a summary of research, prevention, and care-related findings,  
17 including promising new areas for investment; and a report on the  
18 benefits to Washington of its programs to date.

19 (6) The endowment's first annual report must include a proposed  
20 operating plan for the design, implementation, and administration of  
21 an endowment program supporting the purposes of the endowment and  
22 program.

23 (7) The endowment must adopt policies to ensure that all  
24 potential conflicts have been disclosed and that all conflicts have  
25 been eliminated or mitigated.

26 (8) The endowment must establish standards to ensure that  
27 recipients of grants for cancer research, prevention, or care  
28 purchase goods and services from Washington suppliers to the extent  
29 reasonably possible.

30 NEW SECTION. **Sec. 3.** The definitions in this section apply  
31 throughout this chapter unless the context clearly requires  
32 otherwise.

33 (1) "Underrepresented community" or "underrepresented demographic  
34 group" means a community or demographic group that is more likely to  
35 be historically marginalized and less likely to be included in  
36 research and clinical trials represented by race, sex, sexual  
37 orientation, socioeconomic status, age, and geographic location.

38 (2) "Review board" means the Washington state institutional  
39 review board, established pursuant to 45 C.F.R. Part 46, which is the

1 designated institutional review board for the department of social  
2 and health services, the department of health, the department of  
3 labor and industries, and other state agencies.

4 NEW SECTION. **Sec. 4.** Any submissions or proposals submitted to  
5 the review board shall include and the review board shall consider  
6 the following:

7 (1) The ability of the agency to offer trial participants  
8 information in a language other than English;

9 (2) The ability of the agency to provide culturally specific  
10 recruitment materials alongside general enrollment materials;

11 (3) The ability to provide electronic consent when not prohibited  
12 by the granting entity or federal regulation; and

13 (4) Any other evidence of outreach and engagement to increase  
14 participation of underrepresented communities in clinical trials of  
15 drugs or medical devices.

16 NEW SECTION. **Sec. 5.** Any state entity that receives funding  
17 from the national institutes of health to conduct clinical trials of  
18 drugs or medical devices shall adopt a policy concerning the  
19 identification and recruitment of persons who are members of  
20 underrepresented demographic groups to participate in clinical trials  
21 of drugs or medical devices. This policy must include requirements  
22 to:

23 (1) Offer trial participants information in a language other than  
24 English;

25 (2) Provide culturally specific recruitment materials alongside  
26 general enrollment materials;

27 (3) Provide electronic consent when not prohibited by the  
28 granting entity or federal regulation; and

29 (4) Provide other strategies of outreach and engagement to  
30 increase participation of underrepresented communities in clinical  
31 trials of drugs or medical devices.

32 NEW SECTION. **Sec. 6.** A new section is added to chapter 28B.20  
33 RCW to read as follows:

34 (1) If at any time the University of Washington receives funding  
35 from the national institutes of health to conduct clinical trials of  
36 drugs or medical devices, the University of Washington shall adopt a  
37 policy concerning the identification and recruitment of persons who

1 are members of underrepresented demographic groups to participate in  
2 clinical trials of drugs or medical devices. This policy must include  
3 requirements to:

4 (a) Offer trial participants information in a language other than  
5 English;

6 (b) Provide culturally specific recruitment materials alongside  
7 general enrollment materials;

8 (c) Provide electronic consent when not prohibited by the  
9 granting entity or federal regulation; and

10 (d) Provide other strategies of outreach and engagement to  
11 increase participation of underrepresented communities in clinical  
12 trials of drugs or medical devices.

13 (2) For the purposes of this section, "Underrepresented  
14 community" or "underrepresented demographic group" means a community  
15 or demographic group that is more likely to be historically  
16 marginalized and less likely to be included in research and clinical  
17 trials represented by race, sex, sexual orientation, socioeconomic  
18 status, and age.

19 NEW SECTION. **Sec. 7.** A new section is added to chapter 28B.30  
20 RCW to read as follows:

21 (1) If at any time Washington State University receives funding  
22 from the national institutes of health to conduct clinical trials of  
23 drugs or medical devices, Washington State University shall adopt a  
24 policy concerning the identification and recruitment of persons who  
25 are members of underrepresented demographic groups to participate in  
26 clinical trials of drugs or medical devices. This policy must include  
27 requirements to:

28 (a) Offer trial participants information in a language other than  
29 English;

30 (b) Provide culturally specific recruitment materials alongside  
31 general enrollment materials;

32 (c) Provide electronic consent when not prohibited by the  
33 granting entity or federal regulation; and

34 (d) Provide other strategies of outreach and engagement to  
35 increase participation of underrepresented communities in clinical  
36 trials of drugs or medical devices.

37 (2) "Underrepresented community" or "underrepresented demographic  
38 group" means a community or demographic group that is more likely to  
39 be historically marginalized and less likely to be included in

1 research and clinical trials represented by race, sex, sexual  
2 orientation, socioeconomic status, age, and geographic location.

3 NEW SECTION. **Sec. 8.** A new section is added to chapter 70.41  
4 RCW to read as follows:

5 (1) Any hospital that receives funding from the national  
6 institutes of health to conduct clinical trials of drugs or medical  
7 devices shall adopt a policy concerning the identification and  
8 recruitment of persons who are members of underrepresented  
9 demographic groups to participate in clinical trials of drugs or  
10 medical devices. This policy must include requirements to:

11 (a) Offer trial participants information in a language other than  
12 English;

13 (b) Provide culturally specific recruitment materials alongside  
14 general enrollment materials;

15 (c) Provide electronic consent when not prohibited by the  
16 granting entity or federal regulation; and

17 (d) Provide other strategies of outreach and engagement to  
18 increase participation of underrepresented communities in clinical  
19 trials of drugs or medical devices.

20 (2) "Underrepresented community" or "underrepresented demographic  
21 group" means a community or demographic group that is more likely to  
22 be historically marginalized and less likely to be included in  
23 research and clinical trials represented by race, sex, sexual  
24 orientation, socioeconomic status, age, and geographic location.

25 NEW SECTION. **Sec. 9.** Sections 3 through 5 of this act  
26 constitute a new chapter in Title 69 RCW.

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