
SECOND SUBSTITUTE HOUSE BILL 1745

State of Washington

68th Legislature

2023 Regular Session

By House Appropriations (originally sponsored by Representatives Thai, Duerr, Doglio, Ormsby, and Macri)

READ FIRST TIME 02/24/23.

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; adding
5 a new chapter to Title 69 RCW; and creating a new section.

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, in order to increase the identification and
19 recruitment of persons who are members of underrepresented
20 demographic groups to participate in clinical trials of drugs or
21 medical devices, shall:

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

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

26 (3) Provide electronic consent when not prohibited by the
27 granting entity or federal regulation.

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

30 (1) If at any time the University of Washington receives funding
31 from the national institutes of health to conduct clinical trials of
32 drugs or medical devices, in order to increase the identification and
33 recruitment of persons who are members of underrepresented
34 demographic groups to participate in clinical trials of drugs or
35 medical devices, the University of Washington shall:

36 (a) Offer trial participants information in a language other than
37 English;

1 (b) Provide culturally specific recruitment materials alongside
2 general enrollment materials; and

3 (c) Provide electronic consent when not prohibited by the
4 granting entity or federal regulation.

5 (2) For the purposes of this section, "underrepresented
6 community" or "underrepresented demographic group" means a community
7 or demographic group that is more likely to be historically
8 marginalized and less likely to be included in research and clinical
9 trials represented by race, sex, sexual orientation, socioeconomic
10 status, and age.

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

13 (1) If at any time Washington State University receives funding
14 from the national institutes of health to conduct clinical trials of
15 drugs or medical devices, in order to increase the identification and
16 recruitment of persons who are members of underrepresented
17 demographic groups to participate in clinical trials of drugs or
18 medical devices, Washington State University shall:

19 (a) Offer trial participants information in a language other than
20 English;

21 (b) Provide culturally specific recruitment materials alongside
22 general enrollment materials; and

23 (c) Provide electronic consent when not prohibited by the
24 granting entity or federal regulation.

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

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

32 (1) Any hospital that receives funding from the national
33 institutes of health to conduct clinical trials of drugs or medical
34 devices, in order to increase the identification and recruitment of
35 persons who are members of underrepresented demographic groups to
36 participate in clinical trials of drugs or medical devices, shall:

37 (a) Offer trial participants information in a language other than
38 English;

1 (b) Provide culturally specific recruitment materials alongside
2 general enrollment materials; and

3 (c) Provide electronic consent when not prohibited by the
4 granting entity or federal regulation.

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

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

12 NEW SECTION. **Sec. 10.** If specific funding for the purposes of
13 this act, referencing this act by bill or chapter number, is not
14 provided by June 30, 2023, in the omnibus appropriations act, this
15 act is null and void.

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