

2SHB 1745 - S COMM AMD
By Committee on Ways & Means

NOT ADOPTED 04/12/2023

1 Strike everything after the enacting clause and insert the
2 following:

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

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

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

16 (b) Identify barriers to participation in clinical trials by
17 persons who are members of demographic groups that are
18 underrepresented in such trials and employ strategies recognized by
19 the United States food and drug administration to encourage greater
20 participation in clinical trials by such persons; and

21 (c) Make data concerning demographic groups that is collected,
22 reported, and analyzed for the purposes of clinical trials more
23 available and transparent.

24 NEW SECTION. **Sec. 2.** The definitions in this section apply
25 throughout this chapter unless the context clearly requires
26 otherwise.

27 "Washington state review board" or "review board" means the
28 Washington state institutional review board, established pursuant to
29 45 C.F.R. Part 46, which is the designated institutional review board
30 for the department of social and health services, the department of

1 health, the department of labor and industries, and other state
2 agencies.

3 NEW SECTION. **Sec. 3.** The Washington state review board must
4 establish a diversity in clinical trials program to encourage
5 participation in clinical trials of drugs and medical devices by
6 persons who are members of demographic groups that are
7 underrepresented in clinical trials. In developing this program, the
8 review board shall:

9 (1) Review the most recent version of "Collection of Race and
10 Ethnicity Data in Clinical Trials — Guidance for Industry and Food
11 and Drug Administration Staff," published by the United States food
12 and drug administration;

13 (2) Establish a model diversity in clinical trials policy for
14 clinical trials of drugs and medical devices which are conducted by
15 state agencies within the jurisdiction of the review board;

16 (3) Compile and share information and resources in an accessible
17 fashion to assist entities in Washington state that conduct clinical
18 trials of drugs and medical devices to increase participation by
19 persons who are members of demographic groups that are
20 underrepresented in clinical trials, including but not limited to:

21 (a) Information concerning methods for identifying and recruiting
22 persons who are members of underrepresented demographic groups to
23 participate in clinical trials;

24 (b) Links or copies of outside resources related to increasing
25 participation by members of underrepresented demographic groups in
26 clinical trials provided by community organizations or other
27 interested agencies or parties;

28 (c) Contact information for community organizations or other
29 appropriate entities which may be able to provide assistance with
30 efforts to increase participation by underrepresented demographic
31 groups in clinical trials; and

32 (d) Links to websites maintained by medical facilities, health
33 authorities, and other local governmental entities, nonprofit
34 organizations, and scientific investigators and institutions that are
35 performing research relating to drugs or medical devices in this
36 state;

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

1 (5) Beginning July 1, 2024, and every even-numbered year
2 thereafter, submit a report to the governor and health care
3 committees of the legislature concerning the status and results of
4 the diversity in clinical trials program.

5 NEW SECTION. **Sec. 4.** Any state entity that receives funding
6 from the national institutes of health to conduct clinical trials of
7 drugs or medical devices must:

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

15 (2) Provide information to trial participants in languages other
16 than English; and

17 (3) Provide translation services or bilingual staff for trial
18 screening.

19 NEW SECTION. **Sec. 5.** For the purposes of this chapter,
20 demographic groups that are underrepresented in clinical trials may
21 include persons who are underrepresented by race, sex, sexual
22 orientation, socioeconomic status, and age.

23 **Sec. 6.** RCW 43.348.040 and 2018 c 4 s 4 are each amended to read
24 as follows:

25 (1) The Andy Hill cancer research endowment program is created.
26 The purpose of the program is to make grants to public and private
27 entities, including commercial entities, to fund or reimburse the
28 entities pursuant to agreement for the promotion of cancer research
29 to be conducted in the state. The endowment is to oversee and guide
30 the program, including the solicitation, selection, and award of
31 grants.

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

1 (3) The endowment must solicit requests for grant funding and
2 evaluate the requests by reference to factors such as: (a) The
3 quality of the proposed research or program; (b) its potential to
4 improve health outcomes of persons with cancer, with particular
5 attention to the likelihood that it will also lower health care
6 costs, substitute for a more costly diagnostic or treatment modality,
7 or offer a breakthrough treatment for a particular cancer or cancer-
8 related condition or disease; (c) its potential for leveraging
9 additional funding; (d) its potential to provide additional health
10 care benefits or benefit other human diseases or conditions; (e) its
11 potential to stimulate life science, health care, and biomedical
12 employment in the state; (f) the geographic diversity of the grantees
13 within Washington; (g) evidence of potential royalty, sales, or
14 licensing revenue, or other commercialization-related revenue and
15 contractual means to recapture such income for purposes of this
16 chapter; ~~((and))~~ (h) evidence of public and private collaboration;
17 (i) the ability to offer trial participants information in a language
18 other than English; (j) the ability to provide culturally specific
19 recruitment materials alongside general enrollment materials; (k) the
20 ability to provide electronic consent when not prohibited by other
21 granting entities or federal regulations; and (l) other evidence of
22 outreach and engagement to increase participation of underrepresented
23 communities in clinical trials of drugs and medical devices.

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

27 (5) The endowment must issue an annual report to the public that
28 sets forth its activities with respect to the fund, including grants
29 awarded, grant-funded work in progress, research accomplishments,
30 prevention, and care activities, and future program directions with
31 respect to cancer research, prevention, and care. Each annual report
32 regarding activities of the program and fund must include, but not be
33 limited to, the following: The number and dollar amounts of grants;
34 the grantees for the prior year; the endowment's administrative
35 expenses; an assessment of the availability of funding for cancer
36 research, prevention, and care from sources other than the endowment;
37 a summary of research, prevention, and care-related findings,
38 including promising new areas for investment; and a report on the
39 benefits to Washington of its programs to date.

1 (6) The endowment's first annual report must include a proposed
2 operating plan for the design, implementation, and administration of
3 an endowment program supporting the purposes of the endowment and
4 program.

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

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

12 NEW SECTION. **Sec. 7.** A new section is added to chapter 43.348
13 RCW to read as follows:

14 (1) Subject to the availability of amounts appropriated for this
15 specific purpose, the Andy Hill cancer research endowment program
16 shall administer grants to Washington state community-based
17 organizations to conduct outreach and education efforts about
18 clinical trials in underrepresented communities or underrepresented
19 demographic groups. The Andy Hill cancer research endowment may
20 consult with the diversity in clinical trials program established
21 under chapter 69.--- RCW (the new chapter created in section 9 of
22 this act).

23 (2) Grant funding provided under this section may be used to:

24 (a) Design and conduct educational outreach for the purpose of
25 increasing awareness of clinical trials of drugs and medical devices
26 in underrepresented communities or underrepresented demographic
27 groups;

28 (b) Improve health literacy regarding clinical trials through
29 culturally appropriate formats in underrepresented communities or
30 underrepresented demographic groups;

31 (c) Conduct outreach and engagement with underrepresented
32 communities or underrepresented demographic groups to identify
33 barriers to enrolling in clinical trials;

34 (d) Develop culturally appropriate techniques to reduce the
35 barriers identified in (c) of this subsection and establish means to
36 appropriately and effectively identify and recruit persons from
37 underrepresented demographic groups to participate in clinical trials
38 of drugs and medical devices; and

1 (e) Provide resources, information, or proposals for reform to
2 the diversity in clinical trials program created in chapter 69.---
3 RCW (the new chapter created in section 9 of this act) for
4 publication, dissemination, and consideration for inclusion in a
5 report to the governor and health care committees of the legislature.

6 (3) Funding provided under this section may not be used for the
7 direct recruitment of people into specific clinical trials, provided
8 that nothing in this subsection prohibits a grant recipient from
9 facilitating general participation of persons from underrepresented
10 demographic groups in clinical trials, or prohibits grant recipients
11 from entering into agreements with entities that conduct clinical
12 trials of drugs or medical devices to directly assist with
13 identification and recruitment of persons from underrepresented
14 demographic groups to participate in clinical trials, or from using
15 braided funding or funding from other grants to support such
16 identification and recruitment.

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

21 NEW SECTION. **Sec. 8.** (1) The sum of \$75,000, or as much thereof
22 as may be necessary, is appropriated for the fiscal year ending June
23 30, 2024, from the general fund—state appropriation to the Andy Hill
24 cancer research endowment for the purposes of providing grants
25 consistent with section 6 of this act.

26 (2) The sum of \$75,000, or as much thereof as may be necessary,
27 is appropriated for the fiscal year ending June 30, 2025, from the
28 general fund—state appropriation to the Andy Hill cancer research
29 endowment for the purposes of providing grants consistent with
30 section 6 of this act.

31 (3) The appropriations in this section are exempt from matching
32 fund requirements under RCW 43.348.080.

33 NEW SECTION. **Sec. 9.** Sections 1 through 5 of this act
34 constitute a new chapter in Title 69 RCW."

NOT ADOPTED 04/12/2023

1 On page 1, line 1 of the title, after "trials;" strike the
2 remainder of the title and insert "amending RCW 43.348.040; adding a
3 new section to chapter 43.348 RCW; adding a new chapter to Title 69
4 RCW; and making appropriations."

EFFECT: Removes requirements for the Washington State Institutional Review Board (WSIRB) to collaborate with entities performing research related to drugs and medical devices, to identify and recruit members of underrepresented groups to participate in clinical trials, and to establish and maintain a website.

Directs WSIRB to establish a model diversity in clinical trials policy for clinical trials of drugs and medical devices which are conducted by state agencies within the jurisdiction of WSIRB, and to compile and share information and resources in an accessible fashion to assist entities that conduct clinical trials to increase participation by underrepresented groups.

Requires the Andy Hill Cancer Research Endowment (Andy Hill CARE) to administer grants to Washington State community-based organizations to conduct outreach and education efforts related to clinical trials in underrepresented communities or underrepresented demographic groups.

Appropriates \$150,000 GF-S to Andy Hill CARE for the purpose of providing grants to community-based organizations, and exempts this appropriation from matching fund requirements.

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