**1745-S2 AMS WM S2836.1 - NOT FOR FLOOR USE**

**2SHB 1745** - S COMM AMD

By Committee on Ways & Means

**NOT ADOPTED 04/12/2023**

Strike everything after the enacting clause and insert the following:

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

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

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

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

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

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

"Washington state review board" or "review board" means the Washington state institutional review board, established pursuant to 45 C.F.R. Part 46, which is the designated institutional review board for the department of social and health services, the department of health, the department of labor and industries, and other state agencies.

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

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

(2) 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 the review board;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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