2SHB 1745 - S COMM AMD
By Committee on Health & Long Term Care

NOT ADOPTED 04/12/2023

Strike everything after the enacting clause and insert the following:

"NEW SECTION. **Sec. 1.** (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. 2.** 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. 3.** (1) 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 may:

(a) 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;

(b) Collaborate with 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 to assist such investigators and institutions in identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials;

(c) Establish and maintain a website that:

(i) Provides information concerning methods recognized by the United States food and drug administration for identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials; and

(ii) Contains 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;

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

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

(2) Any state entity that receives funding from the national institutes of health to conduct clinical trials of drugs or medical devices must:

(a) 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;

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

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

(3) 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.

Sec. 4. 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. 5.** Sections 1 through 3 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; and adding a new chapter to Title 69 RCW."

EFFECT: Replaces all sections of the bill except Section 2 relating to the Andy Hill Cancer Research Endowment Program with the contents of SSB 5388. While many requirements of SSB 5388 are similar to 2SHB 1745, the new language contains the following substantive differences:

(1) Directs the Washington State Institutional Review Board to establish a Diversity in Clinical Trials Program with duties including providing assistance to research entities in identifying and recruiting members of underrepresented demographic groups to participate in clinical trials, to establish a website, and to consider publication of a biannual report;

(2) Requires any state entity which receives National Institutes of Health (NIH) funding for clinical trials of drugs or medical devices to adopt a policy concerning identification and recruitment of underrepresented demographic groups, to collaborate with community-based organizations, and to use methods to recruit members of underrepresented groups which are recognized by the United States Food and Drug Administration; and

(3) Removes the requirement for entities which receive NIH funding for clinical trials of drugs or medical devices to provide for electronic consent when not prohibited by the granting entity or federal regulation.

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