SSB 5388 - H COMM AMD
By Committee on Health Care & Wellness

NOT CONSIDERED 01/02/2024

Strike everything after the enacting clause and insert the following:

"NEW SECTION. **Sec. 1.** (1) The legislature finds that:

(a) Controlled clinical trials provide a critical base of evidence for evaluating whether a medical product is safe, effective, and efficacious before the product is approved for marketing. The federal 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 generally not well represented in clinical trials;

(b) Communities of color have been working diligently to establish a foundation of trust with government and clinical research with the goal of engaging more trial participants who are members of underrepresented demographic groups;

(c) Joining clinical trials is a difficult and complex process and the lack of trust and awareness of clinical trials and research, in addition to burdens related to transportation, geography, and access, limit trial participants; and

(d) The lack of diversity in clinical trials compounds access to treatment disparities and limits our understanding of the impacts of studied interventions and conditions across the population.

(2) Therefore, the legislature intends to deepen our understanding and knowledge of what communities are underrepresented in clinical trials and the barriers to accessing clinical trials; provide recommendations to increase participation across all populations; and require certain entities conducting clinical trials to offer trial participants information in a language other than English, provide culturally specific recruitment materials alongside general enrollment materials, and provide electronic consent.

Sec. 2. RCW 43.348.010 and 2018 c 4 s 1 are each reenacted and amended to read as follows:

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

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

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

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

(4) "Cancer research" means advanced and applied research and development relating to the causes, prevention, and diagnosis of cancer and care of cancer patients including the development of tests, genetic analysis, medications, processes, services, and technologies to optimize cancer therapies and their manufacture and commercialization and includes the costs of recruiting scientists and establishing and equipping research facilities.

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

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

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

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

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

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

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

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

(13) "Life sciences research" means advanced and applied research and development intended to improve human health, including scientific study of the developing brain and human learning and

development, and other areas of scientific research and development vital to the state's economy.

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

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

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

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

Sec. 3. 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. 4.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

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

(2) "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. 5.** Any submissions or proposals submitted to the review board shall include and the review board shall consider the following:

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

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

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

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

NEW SECTION. **Sec. 6.** Any state entity that receives funding from the national institutes of health to conduct clinical trials of drugs or medical devices shall adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials

of drugs and medical devices. This policy must include requirements to:

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

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

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

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

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

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

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

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

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

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

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

NEW SECTION. **Sec. 8.** A new section is added to chapter 28B.30 RCW to read as follows:

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

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

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

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

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

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

NEW SECTION. **Sec. 9.** A new section is added to chapter 70.41 RCW to read as follows:

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

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

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

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

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

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

NEW SECTION. **Sec. 10.** (1) The department of health, in consultation with the University of Washington, Washington State University, the Andy Hill cancer research endowment, Washington community health boards and initiatives, community-based organizations, and other relevant research organizations, shall analyze and provide recommendations on the following:

(a) What demographic groups and populations are currently represented and underrepresented in clinical trials in Washington, including geographic representation;

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

(c) Barriers for persons who are members of underrepresented demographic groups to participate in clinical trials in Washington, including barriers related to transportation;

(d) Approaches for how clinical trials can successfully provide outreach to underrepresented communities and recommendations on what clinical trials should provide or consider to increase participation in clinical trials; and

(e) A list of appropriate entities that may be able to provide assistance with efforts to increase participation by underrepresented demographic groups in clinical trials.

(2) By December 1, 2023, the department of health shall report to the legislature the results of the analysis and recommendations to increase diversity and reduce barriers for participants in clinical trials.

(3) For purposes of this section, "underrepresented community" or "underrepresented demographic group" means a community or demographic group that is more likely to be historically marginalized and less likely to be included in research and clinical trials represented by race, sex, sexual orientation, socioeconomic status, age, and geographic location.

(4) This section expires December 31, 2023.

NEW SECTION. **Sec. 11.** Sections 4 through 6 of this act constitute a new chapter in Title 69 RCW."

Correct the title.

EFFECT: Removes the underlying provisions of the bill and replaces it with provisions that do the following:

Codifies the Washington State Institutional Review Board (Review Board) and requires the Andy Hill Cancer Research Endowment (Endowment) and the Review Board to evaluate requests and submissions based on the following factors in addition to the current considerations: (1) The ability to offer trial participants information in a language other than English; (2) the ability to provide culturally specific recruitment materials alongside general enrollment materials; (3) the ability to provide electronic consent, if not prohibited; and (4) other evidence of outreach and engagement to increase participation of underrepresented communities in clinical trials for drugs and medical devices;

Requires the University of Washington, Washington State University, and any state agency or hospital that receives funding from the National Institutes of Health to conduct clinical trials of drugs or medical devices to adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials for drugs and medical devices. The policy must include requirements to: (1) Offer trial participants information in a language other than English; (2) provide culturally specific recruitment materials; (3) provide electronic consent, if not prohibited; and (4) provide other strategies of outreach and engagement to increase participation of underrepresented communities;

Requires the Department of Health in consultation with a number of research and community-based entities to study and provide recommendations for increasing access to clinical trials and participation in clinical trials by persons who are members of underrepresented communities; and

Provides intent language.

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