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**SECOND SUBSTITUTE HOUSE BILL 1745**

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**State of Washington 68th Legislature 2023 Regular Session**

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

AN ACT Relating to improving diversity in clinical trials; amending RCW 43.348.040; reenacting and amending RCW 43.348.010; adding a new section to chapter 28B.20 RCW; adding a new section to chapter 28B.30 RCW; adding a new section to chapter 70.41 RCW; adding a new chapter to Title 69 RCW; and creating a new section.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

**Sec.**  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.**  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.**  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.**  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 regulation; and

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

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

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

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

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

NEW SECTION. **Sec.**  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, in order to increase the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials of drugs or medical devices, the University of Washington shall:

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

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

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

(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.**  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, in order to increase the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials of drugs or medical devices, Washington State University shall:

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

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

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

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

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

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

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

(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.**  Sections 3 through 5 of this act constitute a new chapter in Title 69 RCW.

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

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