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2SHB 1745 - S AMD **430**
By Senator Rivers

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 safe and effective before the product is approved for marketing. The United States 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 impact how a person metabolizes a drug. 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. 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. 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, 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;

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

(d) Require certain entities conducting clinical trials to offer trial participants information in a language other than English and provide culturally specific recruitment materials alongside general enrollment materials.

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

(1) "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.

(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. 3.** The Washington state review board shall 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 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:

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

(2) 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;

(3) 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

(4) 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.

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

(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;

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

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

(5) Provide electronic consent when not prohibited by the granting entity or federal regulations.

Sec. 5. 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. 6.** (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) Barriers for persons who are members of underrepresented demographic groups to participate in clinical trials in Washington, including barriers related to transportation; and

(c) Approaches for how clinical trials can successfully partner with community-based organizations and others to provide outreach to underrepresented communities.

(2) By December 1, 2023, the department of health shall report to the legislature the results of the analysis and any 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. 7.** A new section is added to chapter 43.348 RCW to read as follows:

(1) Beginning January 1, 2024, the University of Washington and Washington State University may partner with the Andy Hill cancer research endowment, the department of health, community-based organizations, and other entities to increase the participation of persons who are members of underrepresented demographic groups in clinical trials for drugs or medical devices. If an investigator at the University of Washington or Washington State University is conducting or planning to conduct a clinical trial on a drug or medical device and the University determines that the trial would benefit from specific community outreach and engagement to increase participation of an underrepresented community in the clinical trial, the University of Washington or Washington State University may:

(a) Request the assistance of the department of health and the Andy Hill cancer research endowment to create an outreach plan and coordinate with community-based organizations to provide outreach and engagement; and

(b) Provide the Andy Hill cancer research endowment and the department of health with the following information:

(i) A summary of the clinical trial, including a description of the drug or medical device and any condition or disease that the clinical trial is addressing or targeting;

(ii) Any information on health disparities related to the condition, disease, or related drugs or medical devices, including any demographic groups that may be disproportionately impacted; and

(iii) Any other information that may assist the Andy Hill cancer research endowment, department of health, and community-based organizations in providing outreach and engagement to specific demographic groups or communities.

(2) The requesting university, the Andy Hill cancer research endowment, and the department of health, in collaboration with community-based organizations and other appropriate entities, shall develop a specific community outreach and engagement plan to increase participation of an underrepresented demographic group or community in the clinical trial.

(3) Subject to the availability of amounts appropriated for this specific purpose, the Andy Hill cancer research endowment may administer grants to Washington state community-based organizations to implement the outreach plan and to provide meaningful and real-time community engagement with any demographic groups or communities identified in subsection (1) of this section with the goal of increasing the demographic group's or community's participation in the clinical trial. The community engagement should utilize any recommendations provided by the department of health's report required under section 6 of this act.

NEW SECTION. **Sec. 8.** A new section is added to chapter 28B.20 RCW to read as follows:

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:

(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;

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

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

(5) Provide electronic consent when not prohibited by the granting entity or federal regulations.

NEW SECTION. **Sec. 9.** A new section is added to chapter 28B.30 RCW to read as follows:

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:

(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;

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

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

(5) Provide electronic consent when not prohibited by the granting entity or federal regulations.

NEW SECTION. **Sec. 10.** Sections 1 through 4 of this act constitute a new chapter in Title 69 RCW."

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ADOPTED 04/12/2023

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 section to chapter 28B.20 RCW; adding a new section to chapter 28B.30 RCW; adding a new chapter to Title 69 RCW; creating a new section; and providing an expiration date."

EFFECT: Removes direction to the Washington State Institutional Review Board to establish a model diversity in clinical trials policy, apply for grant funding, and to submit a biannual report.

Expands the definition of underrepresented demographic group to include groups which are historically marginalized and groups which are underrepresented by geographic location.

Expands requirements for state entities which receive National Institutes of Health (NIH) funding to include hospitals that receive NIH funding, and to require provision of culturally specific recruitment materials and to allow electronic consent when not prohibited by the granting entity or federal regulations.

Requires the Department of Health (DOH), in consultation with the University of Washington (UW), Washington State University (WSU), Andy Hill Cancer Research Endowment (Andy Hill CARE), Washington community health boards and initiatives, community-based organizations, and other relevant research organizations, to provide recommendations on specified topics related to diversity in clinical trials and report analysis and recommendations to the Legislature by December 1, 2023.

Allows UW and WSU to partner with Andy Hill CARE, DOH, community-based organizations, and other entities to increase participation of persons who are members of underrepresented demographic groups in specific clinical trials starting January 1, 2024. Subject to funding, Andy Hill CARE may develop an outreach plan and provide grants to community organizations to implement an outreach plan developed to increase participation in the clinical trial. The appropriation of $150,000 to Andy Hill CARE and previous direction for Andy Hill CARE to provide grants to community organizations are removed.

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