
Health Care & Wellness Committee

HB 1745

Brief Description: Improving diversity in clinical trials.

Sponsors: Representatives Thai, Duerr, Doglio, Ormsby and Macri.

Brief Summary of Bill

- Requires the University of Washington, Washington State University, and any hospital or state agency that receives National Institutes of Health Funding for drug and medical device clinical trials to adopt a policy for recruiting members of underrepresented demographic groups to participate in the clinical trial.
- Codifies the Washington State Institutional Review Board (Review Board).
- Requires the Review Board and the Andy Hill Cancer Research Endowment to consider in their evaluation four factors related to increasing participation of underrepresented communities in clinical trials.

Hearing Date: 2/14/23

Staff: Kim Weidenaar (786-7120).

Background:

Institutional Review Boards.

An Institutional Review Board (IRB) is a formally designated group that reviews and monitors research involving human subjects. Research that involves human subjects must receive IRB approval. An IRB is responsible for reviewing research protocols and related materials to ensure protection of the rights and welfare of human subjects in research and may approve, require

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modifications, or disapprove research.

Washington State Institutional Review Board.

The Washington State Institutional Review Board (Review Board) is a designated IRB for a number of different Washington state agencies, including the Department of Children, Youth, and Families, Department of Health, Department of Corrections, Department of Social and Health Services, Health Care Authority, Department of Labor and Industries, and the Office of Financial Management. The WSIRB also serves as a designated IRB for other local and state agencies. The WSIRB is responsible for providing the requisite regulatory review, approval and oversight of research that may involve these state agencies' clients, beneficiaries, patients, wards and state agency employees or these individuals' state agency personal records, in order to ensure the protection of the rights and welfare of human subjects in research.

Andy Hill Cancer Research Endowment.

The Andy Hill Cancer Research Endowment (Endowment), also known as the Andy Hill CARE Fund, makes grants to public and private entities for the promotion of cancer research. The Endowment evaluates requests for funding based on a variety of factors, including:

- the quality of the proposed research or program;
- the potential to improve health outcomes of people with cancer;
- the potential to provide additional health care benefits or benefit other diseases or conditions;
- the potential for leveraging additional funding;
- the potential to stimulate life science, health care, and biomedical employment in Washington;
- the geographic diversity of grantees;
- evidence of potential commercialization-related revenue; and
- evidence of public and private collaboration.

The Endowment is governed by a 13-member board and administered by a private, non-profit corporation with expertise in conducting or managing research granting activities, funds, or organizations.

Summary of Bill:

The Andy Hill Cancer Research Endowment (Endowment) must evaluate requests based on the following factors in addition to the current considerations:

- the ability to offer trial participants information in a language other than English;
- the ability to provide culturally specific recruitment materials alongside general enrollment materials;
- the ability to provide electronic consent; and
- other evidence of outreach and engagement to increase participation of underrepresented communities in clinical trials.

The Washington State Institutional Review Board (Review Board) for state agencies is codified

and defined as the review board established pursuant to 45 C.F.R. Part 46, as 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. Any submissions or proposals submitted to the Review Board must include the same four items the Endowment must evaluate above, which the Review Board must consider.

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 must adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials. The policy must include requirements to:

- offer trial participants information in a language other than English;
- provide culturally specific recruitment materials;
- provide electronic consent; and
- provide other strategies of outreach and engagement to increase participation of underrepresented communities.

"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.

The sections related to the Review Board constitute a new chapter in Title 69.

Appropriation: None.

Fiscal Note: Requested on February 6, 2023.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.