FINAL BILL REPORT
2SHB 1745

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Synopsis as Enacted

Brief Description: Improving diversity in clinical trials.

Sponsors: House Committee on Appropriations (originally sponsored by Representatives Thai, Duerr, Doglio, Ormsby and Macri).

House Committee on Health Care & Wellness
House Committee on Appropriations
Senate Committee on Health & Long Term Care
Senate Committee on Ways & Means

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 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 (DCYF), Department of Health (DOH), Department of Corrections (DOC), Department of Social and Health Services (DSHS), Health Care Authority (HCA), Department of Labor and Industries (L&I), and the Office of Financial Management. The Review Board also serves as a designated IRB for other local and state agencies. The Review Board 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.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not part of the legislation nor does it constitute a statement of legislative intent.

Andy Hill Cancer Research Endowment.
The Andy Hill Cancer Research Endowment (Andy Hill Endowment), also known as the Andy Hill CARE Fund, makes grants to public and private entities for the promotion of cancer research. The Andy Hill 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 Andy Hill 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:

The Review Board for state agencies is codified and defined as the IRB established pursuant to 45 C.F.R. Part 46, as the designated IRB for the DSHS, the DOH, the L&I, and other state agencies.

The 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 underrepresented in clinical trials. The Review Board must compile and share information and resources in an accessible fashion to assist entities in Washington that conduct clinical trials with increasing diversity of participation, including:

- methods for identifying and recruiting persons who are members of underrepresented groups to participate in clinical trials;
- links or copies of outside resources related to increasing participation by members of underrepresented groups provided by community organizations or other interested agencies or parties;
- contact information for community organizations or other appropriate entities which may be able to provide assistance with these efforts; and
- links to websites maintained by medical facilities, health authorities, local governmental entities, nonprofit organizations, and scientific investigators and institutions that are performing research related to drugs or medical devices in Washington.

Any state entity or hospital that receives funding from the National Institutes of Health to

conduct clinical trials of drugs or medical devices, including the University of Washington (UW) and Washington State University (WSU), must:

- adopt a policy concerning identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials that requires investigators to collaborate with community-based organizations and to use methods recognized by the United States Food and Drug Administration;
- provide trial participants information in languages other than English;
- provide translation services or bilingual staff for trial screening;
- provide culturally specific recruitment materials; and
- provide electronic consent when not prohibited by the granting entity or federal regulations.

The Andy Hill Endowment must evaluate requests for grant funding 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;
- the ability to provide electronic consent when not prohibited by other granting entities or federal regulations; and
- other evidence of outreach and engagement to increase participation of underrepresented communities in clinical trials for drugs and medical devices.

The DOH, in consultation with UW, WSU, the Andy Hill Endowment, Washington community health boards and initiatives, community-based organizations, and other relevant research organizations, must analyze and provide recommendations on the following by December 1, 2023:

- the demographic groups and populations that are currently represented and underrepresented in clinical trials in Washington;
- barriers for persons who are members of underrepresented demographic groups to participate in clinical trials; and
- approaches for how clinical trials can successfully partner with community-based organizations to provide outreach.

Beginning January 1, 2024, the UW and WSU may partner with the Andy Hill Endowment, the DOH, community-based organizations, and other entities to increase the participation of persons who are members of underrepresented groups in a clinical trial. If an investigator at UW or WSU determines that a drug or medical device clinical trial would benefit from specific community outreach and engagement to increase participation of an underrepresented community, the university may request the assistance of DOH and the Andy Hill Endowment to create an outreach and engagement plan related to the specific clinical trials. Subject to the availability of appropriated funds, the Andy Hill Endowment may administer grants to Washington community-based organizations to implement the outreach plan and to provide meaningful and real-time community engagement with the goal of increasing the demographic group or community's participation in the clinical trial.

"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.

Votes on Final Passage:

House	95	0	
Senate	49	0	(Senate amended)
House	98	0	(House concurred)

Effective: July 23, 2023