Chapter 69.78 RCW
DIVERSITY IN CLINICAL TRIALS

Sections

RCW 69.78.010 Finding—Policy. (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. [2023 c 426 § 1.]

RCW 69.78.020 Definitions. 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. [2023 c 426 § 2.]

RCW 69.78.030 Diversity in clinical trials program. 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. [2023 c 426 § 3.]

RCW 69.78.040 Requirements for state entities or hospitals conducting clinical trials. 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. [2023 c 426 § 4.]