

Washington State Institutional Review Board

HISTORY

The Department of Social and Health Services has maintained a human subjects protection program since the agency was created in 1970. Initially constituted as the Human Rights Review Desk in DSHS, the DSHS Human Research Review Board was created in the early 1970's. When the Department of Health was established as a separate agency in 1989, the Review Board became a joint entity of DSHS and DOH.

Until April 2001, the Board operated under a federal Multiple Project Assurance of Compliance (MPA) with federal regulations for the protection of human subjects (45 CFR 46): the MPA applied to both DSHS and DOH. Changes in federal procedures in late 2000 required each agency to establish their own Federalwide Assurance (FWA) of compliance with human subject protection regulations. As part of the changed procedures, the Review Board was registered with the federal Office for Human Research Protections as a component of DSHS.

The DSHS and DOH FWAs designate the DSHS Review Board as the official "institutional review board" (IRB) for reviewing research in their respective jurisdictions. The Department of Labor and Industries obtained an FWA in June, 2000, and designated the DSHS Review Board to review the agency's human subjects research. More recently, L&I also designated the UW IRB to review a portion of their research. The Health Care Authority obtained an FWA in January 2012. In March 2013, the Department of Early Learning obtained an FWA, and designated the Washington State IRB to review research in their jurisdiction.

In July 2002, the name of the DSHS Human Research Review Board was changed to the "*Washington State Institutional Review Board (WSIRB)*." The name change reflects a trend toward the Board reviewing research for a growing number of state and local agencies. The new name is consistent with how the Board is identified at local academic and research institutions, where it is commonly known as the "State IRB."

The Washington State IRB is designated on the FWAs of several local health districts: Tacoma-Pierce County Health Department, Spokane Health District, Clark County Health District, Whatcom County Health Department and Kitsap Public Health District. In addition, to reduce duplicative review, IRB Authorization Agreements are in place with the University of Washington (UW), the Fred Hutchinson Cancer Research Center (FHCR), Eastern Washington University, Washington State University, and Seattle Children's Hospital.

HUMAN RESEARCH REVIEW POLICY

Review Board policy and the responsibilities of members and officers of the Board are described in the *Washington State Agency Policy on Protection of Human Research Subjects*. This document represents the outcome of a negotiation process which adapted federal regulations for the protection of human research subjects (45 CFR 46) to the needs of the state agencies. The Review Board's procedures are described in detail in the *Washington State Institutional Review Board Procedures Manual*.

In reviewing research, the Washington State Institutional Review Board determines that:

- the rights and welfare of human subjects are adequately protected;
- risks to individuals are minimized, are not unreasonable, and are outweighed by the potential benefits to them or by the knowledge to be gained; and,
- the proposed study design and methods are adequate and appropriate in light of the stated study objectives.

Research procedures must comply with federal regulations (e.g., 45 CFR Part 46, 45 CFR Part 164), with state laws (e.g., RCW 42.48 and RCW 70.02), and with the Washington Administrative Code (388-04 WAC), as well as other statutes and regulations.