

# SENATE BILL REPORT

## SHB 1622

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As Reported By Senate Committee On:  
Health & Long-Term Care, April 3, 2003

**Title:** An act relating to research in the jurisdiction of a state agency.

**Brief Description:** Clarifying the definition of "research."

**Sponsors:** House Committee on State Government (originally sponsored by Representatives Morrell, Pflug, Cody, Skinner and Clibborn; by request of Department of Social and Health Services).

**Brief History:**

**Committee Activity:** Health & Long-Term Care: 3/25/03, 4/3/03 [DPA, DNP].

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### SENATE COMMITTEE ON HEALTH & LONG-TERM CARE

**Majority Report:** Do pass as amended.

Signed by Senators Deccio, Chair; Winsley, Vice Chair; Franklin, Keiser and Thibaudeau.

**Minority Report:** Do not pass.

Signed by Senators Brandland and Parlette.

**Staff:** Tanya Karwaki (786-7447)

**Background:** The Department of Social and Health Services houses the Washington State Institutional Review Board (WSIRB). Interagency agreements permit the Department of Health and the Department of Labor and Industries to use WSIRB to review human subjects research. As an institutional review board, WSIRB is responsible for protecting the rights and welfare of human research subjects and assuring that the risks of proposed research are reasonable in relation to the potential benefits.

Washington law defines the conditions that WSIRB must determine have been met before a state agency may disclose identifiable personal records (records containing information identifying an individual) for research purposes, without the research subject's informed consent. Confidentiality requirements for this type of disclosure are also specified in statute. Research professionals are prohibited from disclosing personally identifiable research records of state agency clients and employees unless a statutory exception is met.

Changes in federal law have prompted the Department of Social and Health Services to request that state law be harmonized with federal law and with current practices.

**Summary of Amended Bill:** "Research in the jurisdiction of a state agency" is defined as: (1) research conducted by an employee or contractor of a state agency; (2) research sponsored by a state agency; or (3) research involving access to personal information.

The Department of Labor and Industries is added to the list of state agencies authorized to disclose personal information without consent, for research purposes.

A state agency director is authorized to designate the institutional review board of another state agency to review human subjects research for his or her agency.

Research professionals conducting research in the jurisdiction of a state agency are prohibited from disclosing personal identifiable research records of any research subject, unless a statutory exception is satisfied.

**Amended Bill Compared to Substitute Bill:** The striking amendment reinstates existing state law concerning the definition of "research."

**Appropriation:** None.

**Fiscal Note:** Not requested.

**Effective Date:** Ninety days after adjournment of session in which bill is passed.

**Testimony For:** This bill clarifies that research must be objective, capable of replication, and designed to yield reliable and valid results. The state definition of research is harmonized with the federal definition which has been in place since 1991. The bill permits streamlining and efficiency because it allows the Department of Labor and Industries to designate the Washington State Institutional Review Board as its institutional review board (IRB); thus, a duplicative IRB does not have to be created.

**Testimony Against:** This bill expands the information that can be released without the consent of the individual. It also permits almost any project to be considered research. The bill is going in the wrong direction. Concerns: this bill does not address what can be done with the research once it is developed.

**Testified:** Michael Garrick, DSHS (pro); Jean Vanek, Labor and Industries (pro); Jerry Sheehan, ACLU (con); Amber Balch, AWB (with concerns).