

Administrative Policy No. 12.01

Subject: Human Research Review Process

Information Contact: IRB Administrator
Human Research Review Section
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Authorizing Sources: 21 U.S. Code of Federal Regulations (CFR) Parts 50,
45 CFR Part 46 (Protection of Human Subjects)
45 CFR Parts 160-164 (Administrative Data Standards and
Related Requirements) (HIPAA Privacy Rule)
Chapter 42.48 RCW (Release of Records for Research)
Chapter 70.02 RCW (Medical Records—Health Care
Information Access and Disclosure)
Chapter 388-04 WAC (Protection of Human Research Subjects)

Effective Date: November 1, 1987

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Approved By: Original signed by Lori Melchiori
Senior Director, Office of Policy and Rules

Purpose

To protect the rights and welfare of individuals who are subjects of research conducted within the department's jurisdiction.

Background

Federal and Washington state laws require that any entity engaged in human subject research covered by those laws have the research reviewed and approved by an institutional review board (IRB). The department is subject to these laws, and designates the Washington State Institutional Review Board (WSIRB) as the department's IRB, and the human research review section as the department's staff in support of the WSIRB.

Definitions

De-identified information: means that all information that could identify an individual has been removed from the record.

HIPAA: means the Health Insurance Portability and Accountability Act of 1996.

Individually identifiable: means that information that could reveal the identity of the individual remains on the record.

Institutional Review Board (IRB): means a board of professionals and lay persons established in accord with and for the purposes expressed in applicable federal and state law. An IRB is responsible for reviewing and approving research involving human subjects. The Washington State Institutional Review Board (WSIRB) is the IRB for the department.

Limited data set: means protected health information that excludes specific direct identifiers of individuals or of relatives, employers, or household members of the individual. A limited data set can be used only for research, public health, or health care operations.

Non-exempt research: means research that is subject to WSIRB review.

Personal record: means any information obtained or maintained by a state agency which refers to a person and which is declared exempt from public disclosure, confidential, or privileged under state or federal law.

Protected health information (PHI): means individually identifiable health information about an individual that is transmitted or maintained by the department in any form or medium. Individually identifiable health information in department records about an employee or others who are not clients is not protected health information. See [Administrative Policy 05-03](#) for provisions relating only to PHI of clients.

Research: means a systematic investigation designed to develop or contribute to generalizable knowledge.

Policy

- A. The WSIRB is the IRB for the department. The WSIRB must review all proposed non-exempt research within the department's jurisdiction, whether conducted by department employees, department contractors, or outside researchers. The WSIRB review determines whether:
 1. The proposed methods are technically sound and appropriately tailored to provide valid answers to the questions asked.
 2. Subjects' participation is free and voluntary, and their decision to

- participate is based on their fully informed consent.
3. Research risks to subjects are minimized, are not unreasonable, and are either outweighed by potential benefits to subjects, by the knowledge to be gained, or both.
 4. Adequate procedures are established to protect the privacy of subjects and the confidentiality of protected health information and other personal information accessed or obtained during the research.
 5. Special provisions are established to protect research subjects recruited from vulnerable populations and minorities.
 6. Department officials are willing to commit in-kind resources needed for the research.
 7. The research complies with all applicable federal and state laws.
- B. Department personnel, department contractors, outside research professionals, graduate students, and others planning to conduct research within the department's jurisdiction must submit a proposal to the WSIRB.
- C. A researcher must submit their proposal to the WSIRB. Researchers must follow the instructions for submission. If the application is incomplete or not in compliance with the instructions, the WSIRB may find it unacceptable and return it to the researcher.
- D. The WSIRB must inform researchers of the WSIRB's decision. Researchers may submit appeals of negative decisions to the WSIRB. The department may not approve of research that has not been approved by the WSIRB. Administrative concurrence with the review board's approval is required before the research may begin.
- E. The executive secretary, the associate executive secretary, or other human research review section staff must document WSIRB approval to the researcher. The assistant secretary or division director of the program related to the research also must sign-off on the approval.
- F. Researchers who want to use the department's protected health information or individually identifiable personal record information for research must obtain valid signed authorizations or consent from the individuals whose information would be used. If the researcher cannot obtain signed authorizations or consent forms, they may apply to the WSIRB for a waiver of authorization or consent per requirements in applicable federal and state law.
- G. If the Washington State Institutional Review Board approves a waiver of authorization or consent, the researcher and the appropriate department assistant secretary or division director must sign a confidentiality agreement per [RCW 42.48.020](#) (2)(c) before the information may be used or disclosed.

- H. A researcher may use de-identified information for research purposes without further review and approval if the WSIRB finds and documents that the information meets the de-identification standard in [45 CFR 164.514](#) (b)(2).

Procedures

- A. Application forms, the Washington State Agency Policy on Protection of Human Research Subjects, and additional information on the review process, are on the human research review section website (wsirb.wa.gov).
- B. Department employees, department contractors, and outside researchers who have questions about human research review policies and procedures may contact the human research review section at wsirb@dshs.wa.gov for consultation.
- C. The human research review section prepares confidentiality agreements per RCW [42.48.020](#) (2)(c), and obtains the signatures of researchers and the appropriate assistant secretary or division director authorized to approve use or disclosure of protected health information and/or individually identifiable personal record information for research purposes.
- D. The human research review section may direct all requests for an accounting of disclosures of protected health information for research purposes to the DSHS division or administration that disclosed the protected health information.