Washington State Department of Social & Health Services

Transforming lives

Administrative Policy No. 12.01

Subject: Human Research Review Process

Information Contact: IRB Administrator
Human Research Review Section
MS 45205; (360) 902-8075

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

Revised: March 21, 2016

Approved By: original signed by Dana Phelps
Acting Assistant Secretary, Services & Enterprise Support

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 Institution engaged in 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 5.03 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

outweighed by potential benefits to subjects and/or by the knowledge to be gained.

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.
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 on the WSIRB application forms. Researchers must follow the instructions in the application forms. 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 in writing 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 or the Associate Executive Secretary or other HRRS staff must document WSIRB approval by sending a letter to the researcher. The assistant secretary or division director of the program related to the research also must sign the approval letter.

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, he/she 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. The Department will also require a Confidentiality Agreement before a limited data set may be used or disclosed for research.

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 (https://www.dshs.wa.gov/sesa/research-and-data-analysis/human-research-review-section).

B. Department employees, Department contractors, and outside researchers who have questions about human research review policies and procedures should contact the Human Research Review Section at (360) 902-8075 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.