

**INSTITUTIONAL REVIEW BOARD
AUTHORIZATION AGREEMENT**

BETWEEN

WASHINGTON STATE DEPARTMENT OF SOCIAL AND HEALTH SERVICES

AND

WASHINGTON STATE UNIVERSITY

**PART 1
INSTITUTION INFORMATION**

This Institutional Review Board (IRB) Authorization Agreement (IAA) describes the responsibilities of the Institutions that are entering into this IAA. Through this IAA, the Institutions that are entering into this IAA commit that they will adhere to their Federalwide Assurance for the Protection of Human Subjects (FWA).

A. Institution Relying on the Designated IRB:

Institution Name: Washington State University
FWA Number: FWA00002946

B. Institution Providing IRB Review:

Institution Name: Washington State Department of Social and Health Services (DSHS)
FWA Number: FWA00000326
U.S. Department of Health and Human Services (DHHS) IRB Registration Number:
IRB000000093

C. Scope:

This Agreement applies to Washington State University (WSU) studies that are submitted for review by the Washington State Institutional Review Board (WSIRB). Studies that are subject to this IAA are described in Attachment A.

D. Effective Date:

This Agreement is effective as of the date approved and signed by the DSHS Signatory or Delegated Official below.

PART 2 INSTITUTIONAL RESPONSIBILITIES

For studies covered within the Scope of this IAA, WSU and DSHS are responsible for ensuring that their personnel and agents act in accordance with all applicable current, successor and subsequent federal, state and local laws and regulations, the terms and conditions of the institutions' DHHS FWA, the policies of the Washington State Agencies for which the WSIRB serves as a designated IRB, and WSIRB procedures.

Specific Washington State Agency and WSIRB requirements are stated in Part 3 of this IAA.

WSU will permit, upon request by the WSIRB, the inspection of any WSU facilities used in support of the activities covered within the "Scope" of this IAA.

A. The Washington State University will:

1. Ensure that all WSU personnel and agents involved in studies that are subject to this IAA have completed required education and training requirements related to the protection of human research subjects.
2. Verify that the WSIRB has reviewed studies that are subject to this IAA in accordance with applicable requirements.
3. Ensure institutional personnel and agents comply with requirements and oversight established by the WSRB.
4. Ensure WSU personnel and agents follow the WSIRB-approved study protocol.
5. Comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA), 45 CFR Parts 160, 162, and 164, as applicable.
6. Comply with the requirements of 42 CFR Part 50 and 45 CFR Part 94, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, as applicable.
7. Ensure WSU personnel and agents report to the WSRB and to WSU institutional officials: (a) unanticipated problems involving risks to subjects or others, (b) serious or continuing non-compliance, (c) suspension or termination of WSIRB approval, and (d) any other events or circumstances requiring notification.
8. Ensure WSU personnel and agents maintain current copies of their WSIRB-approved study protocols and WSIRB regulatory determinations (initial review, continuing review, amendments, adverse event reports, and final report), all communications with the WSIRB, this IAA, and other relevant information in

accordance with DHHS and Washington State Agency record keeping requirements.

9. Verify the WSIRB has the expertise and policies and procedures needed to review and oversee studies submitted by WSU, in accordance with 45 CFR 46, Sections 107, 103(b)(3), (4) and (5), and 115.

B. The Washington State Department of Social and Health Services will:

1. Verify that WSU personnel and agents involved in studies subject to this IAA have completed required education and training related to the protection of human research subjects.
2. Verify that the WSIRB is properly constituted for reviewing studies subject to this IAA.
3. Fulfill the WSIRB responsibilities identified in DSHS FWA.
4. Fulfill the WSIRB's responsibility for implementation of the provisions of the Health Insurance Portability and Accountability Act (HIPAA), 45 CFR Parts 160, 162, and 164, as applicable.
5. Verify implementation of financial conflicts of interest requirements, as applicable, in accordance with provisions of 42 CFR Part 50 and 45 CFR Part 94, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, as applicable.
6. Provide the Signatory or Delegated Official of WSU with information about the WSIRB, including a list of WSIRB members or expertise and the written procedures for executing WSIRB responsibilities in accordance with paragraph A.9 above.
7. Provide to the Principal Investigators that are conducting studies subject to this IAA, and upon request to WSU, copies of the WSIRB reviews and determinations concerning their studies.
8. Maintain copies of WSIRB-approved study protocols and WSIRB regulatory determinations (initial review, continuing review, amendments, adverse events reports, and final report), all communications with the WSU, this IAA, and other relevant information in accordance with DHHS and Washington State Agency record-keeping requirements.

C. Amendments and Termination:

This IAA may be terminated by either party at any time without cause upon ninety

(90) days written notice.

PART 3
WASHINGTON STATE AGENCY AND WSIRB REQUIREMENTS

- A.** WSU personnel and agents conducting studies that are subject to this IAA will comply with the requirements of the Washington State Agency and WSIRB. These requirements are identified in Part 3, paragraph B.
- B.** When WSU personnel and agents conduct studies that are covered within the “Scope” of this IAA, WSU personnel and agents must comply with the policies and procedures of the WSIRB. These requirements are identified below:
 - 1. Washington State Agency Policy on Protection of Human Research Subjects
 - 2. Washington State Institutional Review Board Procedures Manual

**PART 4
INSTITUTIONAL AGREEMENT**

A. Institution Relying on the Designated IRB

1. Signatory or Delegated Official at Washington State University

Acting in an authorized capacity on behalf of WSU, I assure that WSU will discharge its responsibilities and comply with requirements under this IAA. Furthermore, I am aware that under this IAA that WSU will be relying upon the WSIRB to conduct review on behalf of WSU for studies that are covered within the "Scope" of this IAA.

Signature: 

Date: 3/16/15

Name: Christopher J. Keane, Ph.D.
Institutional Title: Vice President, Office of Research
Telephone Number: 509- 335-3574
Email Address: chris.keane@wsu.edu

Mailing Address:

Office of Research
Washington State University
PO Box 646525, 1815 NE Wilson Road
Pullman, Washington 99164-6525

2. Primary Contact for Human Research Protection at WSU

Name: Malathi Jandhyala, M.S.
Institutional Title: Human Subjects Review Coordinator
Telephone Number: 509-335-3668
Email Address: mjandhyala@wsu.edu

Mailing Address:

Office of Research Assurances
Washington State University
PO Box 643005, Albrook 205
Pullman, Washington 99164-3005

B. Institution Providing IRB Review

1. Signatory or Delegated Official of the Washington State Department of Social and Health Services:

Acting in an authorized capacity on behalf of DSHS, I assure that DSHS and the WSIRB will discharge their responsibilities and comply with requirements under this IAA. Furthermore, I am aware that under this IAA that WSU will be relying upon the WSIRB to conduct review on behalf of WSU for studies that are covered within the "Scope" of this IAA.

Signature:



Date:

3/18/2015

Name: T. Howard Stone, J.D., LL.M., C.I.P.
Institutional Title: Human Protections Administrator
Telephone Number: 360-902-8075
Email Address: howard.stone@dshs.wa.gov

Mailing Address:

Washington Department of Social and Health Services
Human Research Review Section
P.O. Box 45205
Olympia, Washington 98504-5205

2. Primary Contact for Human Research Protection at the DSHS (if different from Part 4, Section B.1 above):

Name:
Institutional Title:
Telephone Number:
Email Address:

Mailing Address:

**ATTACHMENT A
IRB AUTHORIZATION AGREEMENT**

A. Institution Relying on the designated IRB:

Institution Name: Washington State University
FWA Number: FWA00002946

B. Institution Providing IRB Review:

Institution Name: Washington State Department of Social and Health Services (DSHS)
FWA Number: FWA00000326
U.S. Department of Health and Human Services (DHHS) IRB Registration Number:
IRB00000093

C. The institutions entering into this IAA agree that WSU shall rely on the WSIRB for review and continuing oversight of the following activities:

1. WSU studies involving any Washington State Agency personnel or agents conducting study activities, and for which agency the WSIRB provides research oversight, including but not limited to DSHS, the Department of Early Learning, the Department of Health, the Health Care Authority and the Department of Labor & Industries.
2. WSU studies that involve the disclosure or use of records of any Washington State Agency indicated in section C.1 above.
3. WSU studies that involve contact with individuals who reside in or who are housed or confined in any Washington State Agency facility, for which agency the WSIRB provides research oversight, including but not limited to DSHS hospitals, residential facilities or contracted living settings.
4. WSU studies that are sponsored in whole or in part by any Washington State Agency indicated in section C.1 above, either directly with state funds or with federal pass-through funds.