

ACTIVITY REPORT 2011: Washington State Institutional Review Board

Protecting the Rights of Research Participants and Promoting the Ethical Conduct of Research

May 2012

Washington State Department of Social & Health Services

Washington State Department of Labor & Industries

Washington State Department of Health

Washington State Health Care Authority

DSHS

WASHINGTON STATE
Department of Social and Health Services

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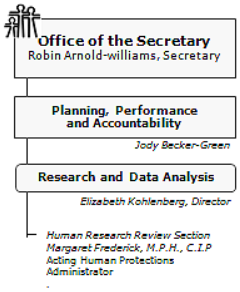
Olympia, WA 98504



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Information About this Publication

Title: Washington State Institutional Review Board, January – December 2011

Abstract: This report provides an overview, organization, and membership of the Washington State Institutional Review Board. It documents the legal authority for the Review Board, and describes major activities during 2011. It also includes a log of all research projects reviewed during this period.

Keywords: Research, Activity Report, Institutional Review Board (IRB), personal record, human subject, research protections, research proposals, confidential records, informed consent, Federalwide Assurance (FWA), Department of Social and Health Services, Department of Labor & Industries (L&I), Department of Health (DOH), Health Care Authority (HCA), Washington State Institutional Review Board (WSIRB).

Category: Institutional Review Board Activities

Geography: Washington State

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LEGAL AUTHORITY FOR WSIRB OPERATIONS

In Washington State, whenever the Department of Social and Health Services, Department of Health, Department of Labor and Industries, or Health Care Authority become engaged in research, the Washington State Institutional Review Board (WSIRB) has jurisdiction over the activity.

This means that research must undergo a formal review by the Board to assure that the rights and welfare of research subjects are protected when the research involves:

- Agency employees as investigator(s)
- Agency clients identified for research by the agency
- Identifiable records held by the agency or its contractors
- Agency employees as subjects
- Agency funding, including pass-through funds
- Agency facilities, such as the state mental hospitals

Washington State Agency Policy on the Protection of Human Research Subjects extends the federal regulations for human subject protections to all research involving human subjects in the departments' jurisdiction, regardless of the funding source.

FEDERAL REGULATIONS

- 45 CFR, Part 46 – Protection of Human Subjects
- 45 CFR, Part 164 – HIPAA Privacy Rule

STATE STATUTES AND RULES

Revised Code of Washington:
- RCW 42.48 – Release of Records for Research
- RCW 70.02 – Medical Records, Health Care Information Access and Disclosure

Washington Administrative Code:
WAC 388-04 Protection of Human Research Subjects

STATE AGENCY POLICIES

- DSHS Administrative Policy 12.01
- DOH Administrative Policy 03.001
- L&I Administrative Policy 9.43

PROMOTING ETHICAL RESEARCH

Dear Reader

The Washington State Institutional Review Board (WSIRB) works to protect the rights and welfare of research participants and to ensure that research conducted within its jurisdiction is sound and likely to produce benefits which are greater than the risks to participants.

The Washington State Institutional Review Board reviews research for four state agencies (DSHS, DOH, HCA, and L&I) and four local health districts. In cooperation with the WSIRB, these agencies ensure compliance with federal human subject protections regulations, state laws, and agency policies. The Human Research Review Section in the Department of Social and Health Services provides administrative support to the WSIRB, while DSHS, DOH, and L&I collectively support the WSIRB mission and fund its operations.

This report provides information about research proposals that WSIRB reviewed during 2011. In addition, the report provides an overview of activities of the Washington State Institutional Review Board. Researchers may find the descriptions of the review process and procedures helpful as they consult with the Review Section during review of their research.

Our website -- http://www.dshs.wa.gov/rda/hrrs/ -- provides additional information about the human research review process, and includes application forms and copies of the *Washington State Agency Policy on Protection of Human Research Subjects* (revised April 14, 2003), and the *Washington State Institutional Review Board Procedures Manual* (revised March 17, 2011).

If you have questions about the WSIRB or the human research review process, please contact Review Section staff at (360) 902-8075 or wsirb@dshs.wa.gov.

We appreciate your support of our efforts to ensure the protection of human research subjects and to promote the ethical conduct of research in Washington State government agencies.

Sincerely,

Margaret Frederick

Margaret Frederick, M.P.H., C.I.P.
Acting Human Protections Administrator
Department of Social and Health Services

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REVIEW BOARD ORGANIZATION AND MEMBERSHIP

Composition of the Review Board
The Washington State Institutional Review Board consists of members with varying backgrounds to promote complete and adequate review of research activities conducted within the jurisdiction of the four Washington State Agencies: Department of Social and Health Services (DSHS), Department of Health (DOH), Labor and Industries (L&I), and Health Care Authority (HCA).

The Review Board is sufficiently qualified through the experience, expertise, and the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of research participants.

Appointment of Board members
Recommendations for Review Board membership are solicited by the IRB Administrator from departmental administrators, Board members, and non-departmental professional and human service agencies and organizations. Candidates for Review Board membership are submitted for consideration and formal appointment by the Secretary of DSHS.

Length of Service
Board members serve a term of one year upon their first appointment. To assure continuity of Board operations, members may be appointed for terms of one, two, or three years following expiration of their first term.

Duties
The Review Board meets 12 times per year at monthly intervals. Board members are expected to attend at least seven meetings per year. Depending on the workload, members spend approximately four to six hours reviewing proposals prior to a Board meeting.

Board members also participate in reviews of proposals that pose no more than minimal risk to subjects ("expedited reviews"). These reviews are conducted by telephone conference between the Primary Reviewer and Review Section staff. Results of these reviews are reported to all WSIRB members.

During review of research proposals, WSIRB members do not participate as representatives of the agency or organization with which they may be affiliated or employed. Rather, each member brings to the review task his/her own expertise, principles, and points of view based on his/her own unique experiences and background.

Conflict of Interest
No Review Board member may participate in the Review Board's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the Review Board. Conflicts of interest may arise for financial or other reasons.

Confidentiality of Materials

All Review Board materials and discussions are considered confidential and shall not be disclosed to or discussed with any individual who is not a member of the Review Board.

For more information: Washington State Institutional Review Board Procedures Manual at http://www.dshs.wa.gov/pdf/ms/rda/hrrs/Procedures.pdf

FUNDED PROJECTS TOTAL $29,757,007

61 new projects reviewed in CY 2011

The chart to the left shows **the source of funding for new studies reviewed** in calendar year 2011. Sixty three percent of all studies reviewed that year were funded by various agencies or foundations. As in previous years, federal agencies were the primary source of funds.

Funds are not necessarily awarded to the agency in which the research would occur. For example, a University of Washington researcher may receive federal funds to conduct research that is in WSIRB jurisdiction.

On the other hand, the Department of Labor and Industries receives federal awards from the National Institute of Occupational Safety and Health (NIOSH) to conduct research, which is also included in these totals. DSHS sometimes receives funds for demonstration projects that include an evaluation (e.g., research) component, while the Department of Health receives funds from the Centers for Disease Control and Prevention to conduct a variety of research projects. The category "state/local government" includes funding by the Washington State Legislature, state agencies, and public universities.

2011

New Administrator Takes the Helm

In February, Doreen Packel assumed the role of Human Protections Administrator (HPA) for DSHS and DOH. Under Ms. Packel, Review Section staff updated the WSIRB Procedures Manual and the Research Application form. During her tenure, Ms. Packel worked with DOH and UW as DOH revised their policy on access to vital records. She also worked with the Health Care Authority (HCA) to establish a new FWA after the Medicaid program moved from DSHS to HCA. Finally, Ms. Packel interviewed potential new Board members. Ms. Packel retired in October. We thank her for her hard work and commitment to the work of the WSIRB.

Distinguished Member

Dolf van den Heuvel marked 10 years serving on the WSIRB. As a token of appreciation for his dedication and continued service, he was presented with a WSIRB jacket and an engraved clock. Dr. van den Heuvel is now a "Distinguished Member" and will continue serving on the WSIRB.

New Members

New appointments to the Board during 2011 include:

January - Håkan Axelsson and Hannah Moats as Non Scientist members.

Mr. Axelsson holds an M.P.A. from the Evergreen State College. He works in DSHS Research and Data Analysis as a communications consultant

Ms. Moats has experience as IRB staff. She is a Certified IRB Professional (CIP). As part of her undergraduate work at Evergreen, she served as WSIRB's intern.

April - Stephen Bao as a Department of Labor and Industries representative. Dr. Bao has extensive research experience and is the Director of the L&I Ergonomics Lab.

October - Brett Parmenter and Alan Puckett.

Dr. Parmenter is a neuropsychologist at Western State Hospital.

Dr. Puckett's background is in social welfare. He is currently the Systems Improvement Advisor at the Casey Family Foundation.

Moving on

Due to increasing professional demands, both Dr. Maureen Marcenko and Dr. David Bonauto transitioned to ad hoc status. Dr. Marcenko later resigned in October after 5 years of WSIRB service.

Dr. Barbara Burns McGrath resigned in September after 11 years of WSIRB service.

We greatly appreciate the dedication that these individuals brought to the human subject protection process.

Applause

Ms. Packel and Maggie Frederick, Review Coordinator, both passed the recertification examination to maintain their CIP designation. The CIP demonstrates an individual's advanced knowledge, understanding, and experience in promoting ethical research practices through IRB administration.

Review Board member Hannah Moats completed her B.A. at The Evergreen State College in May 2011, with an emphasis in public health.

More Change and a Challenge

With Doreen Packel's retirement, Maggie Frederick was appointed Acting Human Protections Administrator in October 2011, leaving Ms. Frederick as the only staff reviewer and delegated signatory official for the WSIRB. While it was at times a challenge to keep up with the increased workload, Ms. Frederick, who has been employed in the Review Section for over 15 years, continued to maintain high quality reviews. At the close of 2011, DSHS managers were in the planning process for hiring a new HPA.

Contacts with Local IRBs

Five Fellows participating in a Western IRB/World Health Organization program to improve human subject protections in other countries attended WSIRB meetings during 2011. The Western IRB attendee was Dr. Rosemary Vazeux. The WHO Fellows hailed from Bangladesh, Korea, Thailand, and China. Fellows are usually health care professionals or IRB members in their home countries.

In June, Review Section staff attended the Regional Conference for IRB Coordinators, which was hosted by the Group Health Research Institute.

Ms. Packel and Ms. Frederick opened discussion with The Evergreen State College about the feasibility of the WSIRB becoming the College's IRB. John McLain, Academic Grants Manager, met with Ms. Packel to discuss requirements and timelines.

Possible Changes to Federal Regulations for Human Subjects Protection

The Office of the Secretary of the Department of Health and Human Services issued an Advance Notice of Proposed Rule Making (ANPRM) in July 2011. The ANPRM, if adopted, would make significant changes in the federal regulations governing human subjects protection. Regulations that would change include 45 CFR Parts 46, 160, and 164, and 21 CFR Parts 50 and 56.

These changes are proposed in order to keep abreast of changes in research volume, focus, and complexity. As research has expanded out of academic institutions and become international in scope, new regulations may be required. New technologies have also expanded research methodology, such as use of the Internet, biobanking, and use of identifiable electronic records. The Office of Human Research Protections states that the changes under consideration "would ensure the highest standards of protections for human subjects involved in research, while enhancing effectiveness of oversight."

Five of the most sweeping changes to the federal regulations are summarized below. The general focus of these changes is to calibrate the level of review required for a given research project to the degree of risk it would pose to subjects. Under this paradigm, if informational risks (privacy, confidentiality) are minimized, the study could move through the review and approval process in a timely, less resource-intensive manner. IRBs could focus the majority of their resources and time on research that poses greater than minimal risk.

1. **Require data security and information protection standards** for identifiable research information and adopt rules prohibiting re-identification of the information.

The proposed regulations would adopt the definitions used in the HIPAA Privacy Rule for individually identifiable, limited datasets, and de-identified information. The WSIRB already applies the HIPAA standards of de-identification to all datasets requested for research.

2. **Revise the requirement for continuation review.**

Proposals that qualified for expedited review would no longer be required to seek continuation approval under the ANPRM. If the initial review of a study was conducted by full committee review, continuing review would not be required if research activities were limited to data analysis or routine clinical follow-up of subjects. Exceptions could be made only if the IRB specifically required continuation review and provided a justification for greater oversight. The exception could be used for both expedited and full committee reviews.

3. **Require regular updates to the categories of research that qualify for expedited review.**

This change in the regulations would also streamline submission requirements for research that qualifies for expedited review.

4. **Revise the criteria for exemption from human subjects protection requirements.**

Under the ANPRM, investigators would be able to file a one-page summary of their proposed research to inform the IRB of their plans. Routine review by IRB staff would not be required, but discouraged. IRBs could perform random retrospective audits, to ensure that such studies are exempt and conform to the new regulations.

The proposed regulations would also exempt all studies involving educational tests, interviews, focus groups, and similar procedures if subjects were competent adults. The data security standards would be required in order to qualify for exemption.

Secondary use of identifiable data or biospecimens in identifiable form would be permitted as exempt research if the data or specimens were collected for non-research purposes and certain consent requirements had been met. Under this revised exempt category, researchers could retain identifiers and could prospectively collect these data or biospecimens. The current exemption applies only to retrospective research.

5. **Generally require signed consent for research use of any biospecimens collected for clinical purposes.**

Patients could sign a standardized consent form to allow future research on biospecimens. The consent form could broadly allow any/all use of specimens, or could be formatted so that patients could chose which uses to permit. The general rule would be that patients must give such consent, although it need not be study-specific and could cover open-ended future research. If such consent were in place, the study may qualify for exemption under the revised regulations.

The ANPRM was open for public comment until October 26, 2011. Review Section staff were not able to provide written comments to HHS, given the increased WSIRB workload. However, some proposed revisions to the regulations do not appear consistent with state statutes for disclosure of identifiable records (RCW 42.48) or the *Washington State Agency for the Protection of Human Research Subjects.* We understand that there will be additional opportunities to comment on the proposed regulations, at which time we hope to provide comments.

The ANPRM may be accessed at http://www.hhs.gov/ohrp/humansubjects/aANPRM2011page.html

ASK THE IRB

I am an agency employee. Do I need WSIRB review for internal research?

Yes. Human subjects review is required for *any* research conducted by the four state agencies or contracted out to another entity.

I already have access to clients/records because I work at the agency. Do I still need WSIRB review for a student project?

Yes. Research for student projects (thesis, dissertation, or class projects) are considered *personal* use of state agency resources, records, or access to clients. These projects go beyond normal work duties and would be conducted for *personal* reasons (e.g., completing a degree or course requirements). If the project would involve DSHS/DOH/L&I/HCA records, clients, facilities, or equipment, or agency employees as subjects, WSIRB review would be required.

My agency is starting a demonstration program or pilot project. We plan to evaluate it to find out if the program is cost-effective and improves client outcomes. Does the evaluation require WSIRB review?

It may. If a project will be implemented on a pilot basis or with a limited pool of clients or limited geographic area, the evaluation may require WSIRB review. In general, evaluations of pilot programs or demonstration projects are considered *research*.

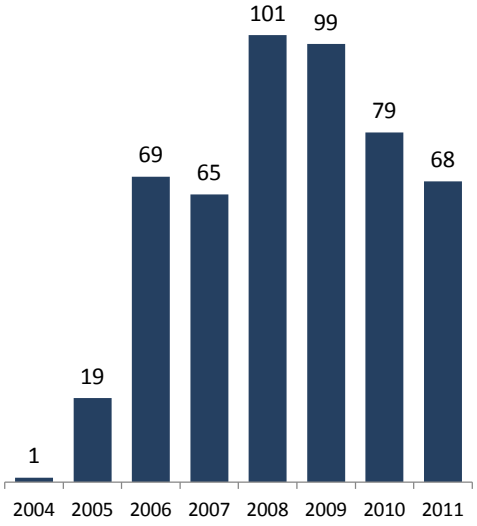
May I request exemption so I can publish or present my results?

If you have already begun the activity, or if you have reached the stage of publication or presentations at conferences, WSIRB staff **cannot** grant exemption. All requests must be submitted before you begin the work. Exemption cannot be granted retroactively by an IRB; journals requiring IRB review may not accept your article for publication.

How do I find out if my project is research that requires WSIRB review, or something else?

If you are not sure if a proposed activity is research, program evaluation, quality improvement, or something else, call WSIRB staff at 360.902.8075 to discuss your plans. WSIRB staff may advise you to submit an Exempt Determination Request for review. You will receive a written response within a few days that informs you if the activity is not considered research, or if it is research that is exempt from WSIRB review.

EXEMPT DETERMINATION REQUESTS



Agency staff and other researchers whose activities are under the jurisdiction of the WSIRB may be asked to submit an Exempt Determination Request.

Review Section staff will evaluate the activity to determine:

- First, is the activity research?
- If it is research, does it involve human subjects?
- If the activity does involve human subjects, does it require WSIRB review?

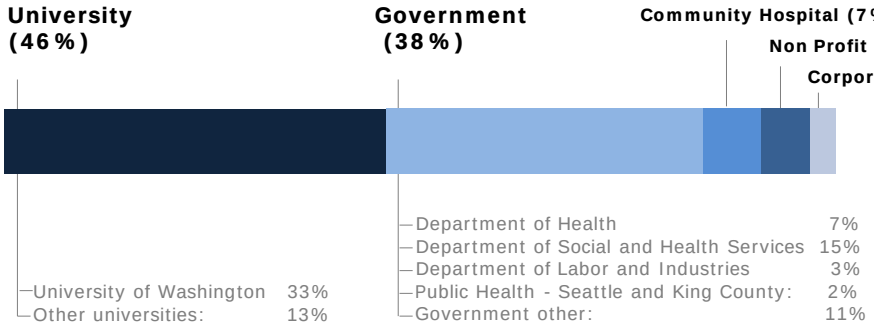
In 2011, 20% of Requests were determined to be research that is *not* exempt.

Review Section staff cannot determine exemption retroactively; all Requests must be submitted **before** an activity has been started.

Chart: This chart shows a continuing trend of requests for exemption over the past few years, as agency staff and other researchers become aware of the exempt determination process.

RESEARCHER AFFILIATION

January – December 2011 | Proposals Reviewed: 61

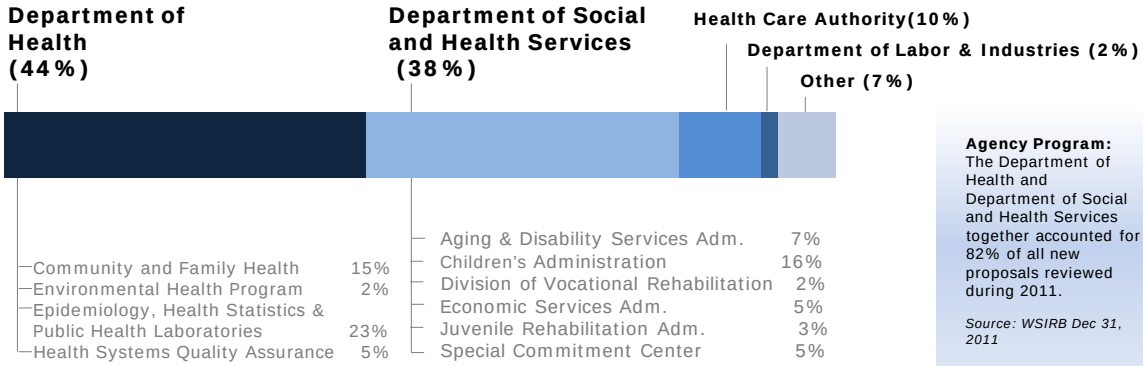


Researcher Affiliation: Forty six percent of the principal investigators were university-based, with the University of Washington accounting for the large majority.

Source: WSIRB Dec 31, 2011

AGENCY PROGRAM

January – December 2011 | Proposals Reviewed: 61



Agency Program: The Department of Health and Department of Social and Health Services together accounted for 82% of all new proposals reviewed during 2011.

Source: WSIRB Dec 31, 2011

These charts provide information about the proposals submitted for review by the WSIRB, by agency program and researcher affiliation.

Each proposal is assigned to a state agency program area by Review Section staff. The program area assignment generally reflects the primary source of research subjects or the state agency program in which the research will occur. For example, a researcher who submits a request to obtain identifiable mental health treatment records would be coded as "Aging & Disability Services," as that DSHS program area is the source of research subjects. Research proposals submitted by state agencies are generally coded as the program area in which the researcher is employed. So, for example, research applications submitted by SHARP in the Department of Labor and Industries are coded as such.

The few research proposals that are not otherwise in the jurisdiction of the WSIRB are coded as "Other"; these proposals are reviewed at the request of the Investigator's home institution.

Each proposal is also coded to track the professional affiliation of the Principal Investigator. The WSIRB reviews applications submitted by researchers' at large corporate research organizations such as Westat, The RAND Corporation, and RTI International. Proposals are also submitted by faculty from academic institutions across the country and by state and federal agencies, such as the Centers for Disease Control and Prevention. If research will be conducted for educational purposes, generally either a Master's degree or doctorate, researcher affiliation is coded as the academic institution from which the degree would be granted.

ACTIVITY REPORT, JANUARY - DECEMBER 2011

The following research applications were submitted for WSIRB review from January through December 2011. They are categorized by the Administration in which the research will occur or the source of research subjects (see page 7 of this Report for an explanation). The "status" code indicates each application's status at the end of 2011. Projects that are cancelled may be resubmitted, and are then assigned a new study number. Cancellation usually occurs due to non-response by the researcher, a decision by the researcher to submit a completely revised proposal in terms of design or methodology, or, in a few cases, the research is ultimately not conducted.

DEPARTMENT OF SOCIAL AND HEALTH SERVICES	Status	Study #
Aging and Disability Services Administration		
WA-CARES Evaluation Barbara Lucenko, Ph.D. | DSHS Research and Data Analysis	Cancelled	D-012411-S
WA-CARES Evaluation Barbara Lucenko, Ph.D. | DSHS Research and Data Analysis	Approved	D-062211-S
Medical Symptom Validity Test (MSVT) Amber Simpler, Ph.D. | Western State Hospital	Approved	D-072211-S
Academic Performance and Long-Term Educational and Career Outcomes for Children and Youth with Behavioral Health Needs Elizabeth Coker M.S.Ed., Ph.D. DSHS Research and Data Analysis	Approved	D-092811-S
Children's Administration		
Economically Disconnected Families in the Child Welfare System Jennifer Romich, Ph.D. University of Washington School of Social Work | West Coast Poverty Center	Approved	D-010411-S
Foster Children in Washington State: Barriers to Dental Care Molly Melbye, D.D.S. University of Washington School of Dentistry	Approved	D-012111-S
Addressing Disparities in Learn the Signs | Act Early: Reaching Families at Risk for Maltreatment Daniel Crimmins, Ph.D. | Georgia State University	Cancelled	D-022511-S
Evaluation of the Catholic Family and Child Service (CFCS) Family Connections Demonstration Project Peter Selby, Ph.D. | Tri-West Group, L.L.C.	Cancelled	D-022611-S
Examining the Efficiency in Washington's Juvenile Dependency Court System Jesse Russell, Ph.D. National Council of Juvenile and Family Court Judges	Approved	D-031511-S
Assessment of Childhood Sexual Behavior Problems Kelley Simmons Jones, MA, LMHC – doctoral student Antioch University, Seattle	Cancelled	D-091911-S
The Long Term Family Study - A Continuation Examining Drug Use Trajectories and the Transition to Adulthood among Maltreated Youth Diana English, Ph.D. University of Washington School of Social Work	Cancelled	D-110711-S
Protection Program Mobile Phone Real Time Photo Review Study Rebecca Wiester, M.D. | Seattle Children's Hospital	Cancelled	D-110911-S

A Case Study of a Chronically Referred Family to Child Welfare Services: Experience with an Evidence-Based Parenting Intervention Douglas Klinman, B.A. – graduate student University of Washington	Cancelled	D-122011-S
The Long Term Family Study - A Continuation Examining Drug Use Trajectories and the Transition to Adulthood among Maltreated Youth Diana English, Ph.D. University of Washington School of Social Work	Conditionally Approved	D-122811-S

Division of Vocational Rehabilitation

Improving Employability Skills for Students with Developmental Disabilities Michael Dunn, Ph.D. | Washington State University, Vancouver	Cancelled	D-101811-S

Economic Services Administration

Net Impact and Cost-Benefit Evaluation of Washington State's Workforce Training System David Pavelchek, M.A., M.P.A. Workforce Training and Education Coordinating Board	Cancelled	D-082911-S
Net Impact and Cost-Benefit Evaluation of Washington State's Workforce Training System David Pavelchek, M.A., M.P.A. Workforce Training and Education Coordinating Board	Cancelled	D-121211-S
Correlates of Educational Achievement for Children Receiving Economic Services in Washington State Elizabeth Coker, M.S.Ed., Ph.D. | DSHS Research and Data Analysis	Conditionally Approved	D-121511-S

Juvenile Rehabilitation Administration

Improving Immediate Substance Abuse Treatment Outcomes for Incarcerated Adolescents: Using Family Participation Michael Campbell, B.A. – graduate student Central Washington University	Cancelled	D-032211-S
Second National Survey of Youth in Custody David Cantor, Ph.D. | Westat	Approved	D-102811-S

Special Commitment Center

Assessing Personality Characteristics on an Archival Sample of Sexually Violent Predators Using the Rorschach Inkblot Test Bruce Duthie | DSHS Special Commitment Center	Approved	D-031611-S
An Archival Study of Psychopathy among Civilly Committed Sexually Violent Predators Transferred to Less Restrictive Alternative Placements Emily Zimmerman, Psy.D. | DSHS Special Commitment Center	Approved	D-040811-S
An Archival Comparison of Respondent and Petitioner Experts' Sexually Violent Predator Evaluations Julia McLawsen, Ph.D. | DSHS Special Commitment Center	Approved	D-092311-S

DEPARTMENT OF HEALTH	Status	Study #
Community and Family Health		
Seattle Secondary Data Analyses Hanne Thiede, D.V.M., M.P.H. Public Health - Seattle and King County	Approved	D-020811-H
Determine the Potential Usefulness of the CHILD Profile Immunization Registry Data as a Means to Enhance Pertussis Surveillance Jennifer Merte, M.P.H. | Clark County Public Health	Approved	D-032511-H
Immunization Information System Data Quality Project Rebecca Hills M.S.P.H. | University of Washington	Approved	D-033011-H
Validating a Childhood Vaccine Registry (VCVR) David Grossman, M.D., M.P.H. | Group Health Research Institute	Approved	D-040111-H
An Examination of the Spatial Distribution of Cancer Incidences in Washington Rosanna Lee, M.A. – graduate student University of Washington	Cancelled	D-051811-H
Epidemiologic Profile of Refugees in Washington State Laura Vonnahme, M.P.H. Centers for Disease Control & Prevention– Seattle	Cancelled	D-052311-H
Impact of Targeted Intervention of Influenza Vaccination for Limited English Proficient Children with Asthma in the Emergency Department Beth Ebel M.D., M.Sc., M.P.H. University of Washington School of Medicine	Cancelled	D-072111-H
Lymphoma Risk: A Consequence of Immune Suppression or Stimulation? Kristen Hayward, M.D. | Seattle Children's Hospital	Cancelled	D-082211-H
Rotavirus Coverage and Birth and Maternal Risk Factors for Delayed or Incomplete Vaccine Series among Children Born during 2010 Kathleen Stigi, M.P.H. | DOH Communicable Disease Epidemiology	Approved	D-102111-H
Environmental Health Programs		
Maintaining and Improving Pesticide-Illness Surveillance in Washington State Joanne Prado, M.P.H. DOH Environmental Health Programs	Approved	D-030711-H
Epidemiology, Health Statistics, and Public Health Laboratories		
Washington State Boating Death and Injury Analysis Melissa Schiff, M.D., M.P.H. | University of Washington	Approved	D-011811-H
Long-term Outcomes of King County Emergency Medical Services for Cardiovascular Disease Thomas Rea, M.D., M.P.H. | University of Washington	Approved	D-013111-H
Healthy Youth Survey 2012 Lillian Bensley, Ph.D. DOH Epidemiology, Health Statistics, and Public Health Laboratories	Approved	D-022411-H
High Throughput Methods to Measure Disparities in Childhood Exposure to Tobacco Logan Spector, Ph.D. | University of Minnesota	Approved	D-030111-H
The University of Washington Twin Registry Fetal Origins Project Eric Strachan, Ph.D. | University of Washington School of Medicine	Cancelled	D-041911-H

Ground Level Falls in the Elderly Lisa McIntyre, M.D. University of Washington | Harborview Medical Center	Approved	D-051211-H
Contribution of Neighborhood Factors to the Risk of Influenza-Associated Pediatric Mortality Joshua Clayton M.P.H. University of Michigan School of Public Health	Approved	D-061011-H
Adolescent Trauma Recovery and Stress Disorders Collaborative Care (ATRSCC) Model Program Trial Douglas Zatzick, M.D. University of Washington School of Medicine	Cancelled	D-072011-H
Describing Pneumococcal Disease in Washington State Chas DeBolt, R.N., M.P.H. | Department of Health	Approved	D-090211-H
Multiple Drug Resistant Organism Colonization Point Prevalence Survey David Birnbaum, Ph.D. DOH Epidemiology, Health Statistics, and Public Health Laboratories	Cancelled	D-090911-H
The University of Washington Twin Registry Fetal Origins Project Eric Strachan, Ph.D. | University of Washington	Conditionally Approved	D-101211-H
Robin Sequence: Descriptive Epidemiology of and Risk Factors for a Multifactorial Developmental Sequence Kelly Evans, M.D. | Seattle Children's Hospital	Approved	D-102911-H
Exploring the Relationship of Vitamin D and Childhood Brain Tumors Parveen Bhatti, Ph.D. | Fred Hutchinson Cancer Research Center	Approved	D-120811-H
Risk Reduction Education in Patients with Prior Preterm Birth Thomas Benedetti, M.D., M.H.A. | University of Washington	Deferred	D-123111-H

Health Systems Quality Assurance

The Effects of Economic Recession on Traumatic Injury Patterns Patricia Ayoung-Chee, M.D. University of Washington | Harborview Medical Center	Approved	D-080311-H
First Responder Traumatic Brain Injury Quality Improvement Monica Vavilala, M.D. Harborview Injury Prevention and Research Center	Cancelled	D-091611-H
Trauma Care and Outcomes Among Washington's American Indian | Alaska Native Populations Victoria Warren-Mears, Ph.D. Northwest Portland Area Indian Health Board	Conditionally Approved	D-111811-H

DEPARTMENT OF LABOR AND INDUSTRIES

	Status	Study #

Safety and Health Assessment and Research for Prevention (SHARP)

Developing an Intervention to Reduce Workplace Violence in Healthcare Settings Nanette Yragui, Ph.D. L&I Safety and Health Assessment and Research for Prevention	Approved	D-082511-L

HEALTH CARE AUTHORITY	Status	Study #
ADVICE: Lung Cancer Study Scott Ramsey, M.D., Ph.D. Fred Hutchinson Cancer Research Center	Approved	D-042111-S
Evaluation of the Washington State Guidelines on Opioid Dosing for Chronic Pain Gary Franklin, M.D., M.P.H. University of Washington School of Public Health	Cancelled	D-061711-S
Accelerating Adoption of Comparative Effectiveness Findings in Clinical and Organizational Practices Stephen Crystal, Ph.D. Rutgers, The State University of New Jersey	Cancelled	D-062411-A
First Steps Database Mary Lawrence Cawthon, M.D., M.P.H. DSHS Research and Data Analysis	Approved	D-092711-A
Accelerating Adoption of Comparative Effectiveness Findings in Clinical and Organizational Practices Stephen Crystal, Ph.D. Rutgers, The State University of New Jersey	Approved	D-110211-A
Evaluation of the Washington State Guideline on Opioid Dosing for Chronic Pain Gary Franklin, M.D., M.P.H. University of Washington School of Public Health	Approved	D-110311-A

OTHER**	Status	Study #
Criminal Profiles and Demographic Characteristics of Family Violence Offenders Sarah Veele-Brice, Ph.D. | Administrative Office of the Courts	Approved	D-050211-U
Prospective Observation of Rapid | Short Acting Insulin Therapeutic Errors Management Study (PORSA-ITEM) Curtis Elko, Pharm.D. | Washington Poison Center	Approved	D-071011-U
Thurston County Girls Circle Evaluation Suzanne Kerns, Ph.D. University of Washington School of Medicine	Approved	D-102711-U
Migrant Student Basic Research Paul McCold, Ph.D. | Office of Superintendent of Public Instruction	Cancelled	D-122311-U

** Reviewed at the request of the researcher's home institution; not otherwise in WSIRB jurisdiction.

History of Human Subjects Protection
IN THE UNITED STATES

1940

1945
Nuremberg Trials

- Medical experimentation abuses by Nazi doctors comes to public attention
- United States, Great Britain, France and Russia charge 24 men and six organizations with systematic murder of millions of people
- Nuremberg Code results – first legal attempt to deal with ethical issues of modern research

1950

1953
NIH Requirement

- National institutes of Health requires that all proposed clinical research projects at its center in Bethesda obtain approval from a protection of human subjects review panel

1964
Declaration of Helsinki

- Declaration of Helsinki is adopted by the World Medical Association – a statement of ethical principles to provide guidance to physicians and others conducting medical research

1960

1966
First Regulations

- United States Public Health Service issues its first set of regulations extending a review requirement to all "extramural" research supported by the agency
- Revisions in 1971 and 1974 lead to Institutional Review Boards (IRBs) at hundreds of institutions receiving federal funding for research

1972
Tuskegee Study

- Public disclosure prompts the cancellation of 40-year government-supported Tuskegee Syphilis Study in which 300 black rural men were left untreated for diagnosed syphilis, even after effective antibiotics became available
- Public Law 93-348 results, establishing the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

1970

1979
Belmont Report and Title 45 CFR 46

- The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research publishes recommendations, known as the Belmont Report, that serve as the basis for revised federal regulations published in the Federal Register in 1979
- Three general ethical principles provide a framework for human subjects research:
  1. **Beneficence:** To maximize benefits for science, humanity, and research participants and to avoid or minimize risk or harm
  2. **Respect:** To protect the autonomy and privacy rights of participants
  3. **Justice:** To ensure the fair distribution among persons and groups of the costs and benefits of research

1980

1991
Common Rule

- The DHHS regulations for human subjects protection in 45 CFR Part 46 are codified by 14 federal agencies, often referred to as "The Common Rule"

1990

1996 *and after*
Unified Standards

- International Conference on Harmonization, Good Clinical Practice Guidelines unifies standards for European Union, Japan, and United States to facilitate mutual acceptance of clinical trial data by respective regulatory authorities

2000

1998
45 CFR Update

- The federal Department of Health and Human Services adopts revised expedited review categories in 45 CFR Part 46

2001
Pregnant women

- The federal Department of Health and Human Services issues revised Subpart B, Additional Protections for Pregnant Women, Human Fetuses and Neonates permitting research with pregnant women, in most cases leaving decision-making to the woman

2003
Health Insurance Portability and Accountability Act (HIPAA)

- HIPAA, implemented in mid-April, is the first national standard for health information privacy. HIPAA rules do not apply to all health information.

SOURCE (through 1991): University of Washington, Human Subjects Division. Based on history compiled by the Fordham University Center for Ethics Education, NY.

Information after 1991 provided by DSHS Human Research Review Section

Protecting the Rights of Research Participants

Promoting the Ethical Conduct of Research

For more information, please contact the DSHS Human Research Review Section
360.902.8075 or email: wsirb@dshs.wa.gov

DSHS Human Research Review Section website:
www.dshs.wa.gov/rda/hrrs

Washington State Department of Social & Health Services

Washington State Department of Labor & Industries

Washington State Department of Health

Washington State Health Care Authority