





## ACTIVITY REPORT

# **Washington State Institutional Review Board**

**January – December 2009** 











### **DSHS**

WASHINGTON STATE

Department of Social
and Health Services

#### Headquarters located at:

14<sup>th</sup> and Jefferson Street Olympia, WA 98504



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#### Information About this Publication

Title: Washington State Institutional Review Board, January - December 2009

**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 2009. 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), Washington State Institutional Review Board (WSIRB).

Category: Institutional Review Board Activities

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#### LEGAL AUTHORITY FOR WSIRB OPERATIONS

In Washington State, whenever the Department of Social and Health Services, the Department of Health, or the Department of Labor and Industries 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

#### RESPONSIBLE 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 three state agencies (DSHS, DOH, 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 the three state agencies collectively support the WSIRB mission and fund its operations.

This report provides information about research proposals that WSIRB reviewed during 2009. 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 December 18, 2008).

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,

Michael A. Garrick, Ph.D.
Human Protections Administrator
Department of Social and Health Sorvice

Department of Social and Health Services

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<sup>&</sup>lt;sup>2</sup> Alternate member

#### 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 three Washington State Agencies: DSHS, DOH, and L&I.

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 Executive Secretary 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.

During the review of research proposals, 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.

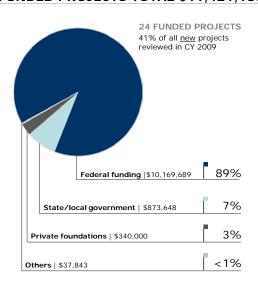
#### **Confidentiality of Materials**

All Review Board materials 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 \$11,421,180**



The chart to the left shows the source of funding for new studies reviewed in calendar year 2009. Forty-one 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, with 13 of the 24 projects funded by the Department of Health and Human Services

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 Institutes of Occupational Safety and Health (NIOSH) to conduct research, which is also included in these totals. DSHS also 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 to conduct a variety of research projects. The category "state/local government" includes funding by the Washington State Legislature, state agencies, or public universities.

# 2009

#### **WSIRB** Membership

New members: The WSIRB welcomed two new members in October 2009: Stephanie Barton, MA, and Annie Keeney. Ms. Barton works in quality assurance in DSHS Health and Recovery Services. Ms. Keeney until recently was a recreational therapist at Eastern State Hospital; she is pursuing an MSW at Eastern Washington University. Ms. Barton and Ms. Keeney are both "non-scientist" members of the Review Board.

Milestones: Two Review Board members--Chair Hanne Thiede and member M Patricia deHart--marked 10 years serving on the WSIRB. Both Dr. Thiede and Dr. deHart joined the Review Board in January 1999. As a token of appreciation for their dedication and continued service, each was provided with a WSIRB jacket and an engraved clock.

Foreign Service: Board Chair Hanne Thiede traveled to Zambia to work on local public health issues as part of a program coordinated by the National Association of State and Territorial Health Directors. Board member Maria Courogen has also traveled with ASTHD to India, Zambia, and Haiti.

Moving on: Samantha Asbjornsen, MSW, resigned from the Review Board when she changed employment in late 2009. Non-scientist member Nancy Sclater resigned from the Review Board due to increasing work commitments. Longtime member Cindy Bouillon-Jensen, MA, CIP, also resigned due to increasing responsibilities as a member of a commercial IRB, Western IRB (WIRB). Ms. Bouillon-Jensen served on the Review Board for 15 years and was DSHS Human Research Review Section staff for two years.

#### Quality Improvement Activities

**Review of Updated** 

Applications: The WSIRB implemented a new procedure in which researchers will be required to submit an updated protocol if their research continues to contact human subjects 5 years after the initial review. This process will help ensure that ongoing research is consistent with changes in agency or WSIRB policy, and changes in regulatory requirements or guidance from the federal Office for Human Research Protections. About a dozen active studies may require review of an updated protocol over the next year.

Electronic Reviews: The WSIRB continues to move more of its communications to an electronic format. Investigators now receive WSIRB decisions as pdf documents sent via email. Requests for continuation, amendment requests, and requests for exemption are all submitted to the WSIRB electronically; paper submissions are no longer necessary. Electronic communication ensures more timely notification of IRB decisions, particularly for researchers on the East Coast or in foreign countries. It also reduces the overall printing, copying, and mailing costs for investigators and the WSIRB.

WSIRB Member Training: The WSIRB continued to conduct inservice training for Review Board members at convened meetings. In-service training is designed to ensure that Board members remain current with regulatory issues and other aspects of human subject protections, focusing on the "how-to" of review.

The seven training sessions conducted during 2009 focused on how to present a continuation approval request; waivers of consent and waivers of documentation of consent; IRB staff observation of research with juvenile offenders;

WSIRB member responsibilities and retention of Review Board materials; how to present a study amendment request; internet surveys; privacy and confidentiality in research; and offering incentives for research participation.

All in-service training materials are posted on the WSIRB website. A new checklist for presenting amendment requests was developed for WSIRB members in 2009.

The Review Section offers free web-based training in human subjects protection via the Collaborative IRB Training Initiative (CITI) at the University of Miami. Human subjects training requirements were individualized in 2009 so that each trainee completes modules related to his/her research function. Principal Investigators are required to complete a more comprehensive training than research interviewers or statisticians. Training for WSIRB members was also customized according to tenure. CITI now includes a module specifically for new IRB members.

#### Contacts with Local IRBs:

Review Section and WSIRB staff Maggie Frederick gave a presentation at the University of Washington Human Subjects Division in August 2009. She provided an in-depth overview of WSIRB jurisdiction to IRB coordinators and administrators.

Fellows participating in a Western IRB/World Health Organization program to improve human subject protections in other countries attended WSIRB meetings during 2009. Western IRB attendees included Paul Newton, JD, CIP, Director of Regulatory Affairs, WIRB, and three Fellows from South Korea. Fellows are usually health care professionals or IRB members in their home countries.

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#### **ASK THE IRB**

















# I am a DSHS/DOH/L&I employee. Do I need WSIRB review for internal agencysponsored research?

Yes. Human subjects review is required for *any* research conducted by the three state agencies or contracted out to another entity. See *Washington State Agency Policy for Protection of Human Research Subjects*, April 2003, Section II.

I want to do a student project and I already have access to clients/records because I work at DSHS/DOH/L&I. Do I need WSIRB review even though I already have access as part of my job?

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

My division of DSHS/DOH/L&I is implementing a demonstration program or pilot for our clients. The program will be evaluated to find out if it's cost-effective and improves client outcomes. Does the evaluation require WSIRB review?

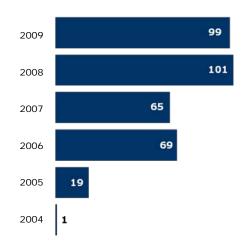
It may. If a demonstration program will be implemented on a pilot basis to a limited pool of clients or limited geographic area, the evaluation of the pilot program may require WSIRB review. In general, evaluations of pilot programs or demonstration projects are considered *research*.

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

If you are unsure whether a proposed activity is research, program evaluation, surveillance, quality assurance/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 <u>not</u> considered research, or if it is research that is exempt from WSIRB review.

**NOTE**: It is important to submit a request for exemption **before** you start the project; a request for exemption cannot be made retroactively.

#### **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:

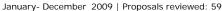
- Is the activity research?
- If it is research, does it involve human subjects?
- If the activity does involve human subjects, does it require WSIRB review?

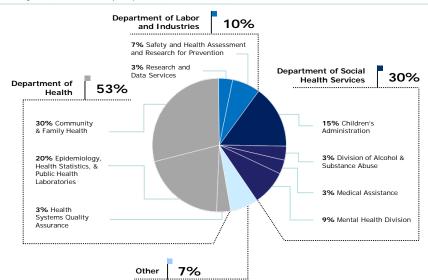
Currently about 10% of Requests are determined to be research that is not exempt.

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

**Chart:** This chart demonstrates the dramatic increase in requests for exemption over the past few years, as agency staff and other researchers become aware of the exempt determination process.

#### **AGENCY PROGRAM**





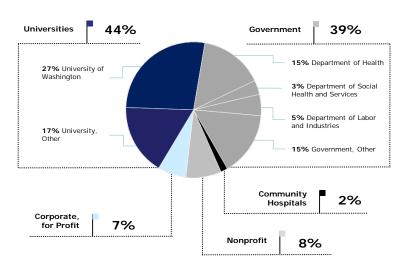
#### AGENCY PROGRAM:

The Department of Social and Health Services and Department of Health together accounted for 83% and Department of Labor and Industries had 10% of all the new proposals reviewed during 2009.

Source: WSIRB Dec 31, 2009

#### RESEARCHER AFFILIATION

January - December 2009 | Proposals Reviewed: 59



#### RESEARCHER AFFILIATION:

Forty four percent of the principal investigators were university-based, with the University of Washington accounting for the large majority. The other 56% of researchers were affiliated with Government, Corporate, Community Hospitals, and Nonprofit.

Source: WSIRB Dec 31, 2009

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 hospital discharge records would be coded as "Epidemiology, Health Statistics, and Public Health Laboratories," as that DOH 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 will be granted.

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#### **ACTIVITY REPORT, JANUARY - DECEMBER 2009**

The following research applications were submitted for WSIRB review from January through December 2009. They are categorized by the program area in which the research will occur or the source of research subjects (see page 6 of this Report for an explanation). The "status" code indicates each application's status at the end of 2009. 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 #
Children's Administration		
Child Welfare Placements and DMC in Juvenile Justice Joseph Ryan, M.S.W., Ph.D.  University of Illinois / School of Social Work	Cancelled	D-013009-S
<b>KEEP Evaluation</b> Shannon Dorsey, Ph.D.  University of Washington / Public Behavioral Health & Justice Policy	Approved	D-022809-S
Foster Care to College Partnership Mason Burley, M.P.A.  Washington State Institute for Public Policy	Completed	D-031909-S
Child Welfare Placements & DMC in Juvenile Justice Joseph Ryan, M.S.W., Ph.D.  University of Illinois	Approved	D-063009-S
Juvenile Court Mental Health Data Tracking Project Sarah Cusworth Walker, Ph.D.  UW / Public Behavioral Health & Justice Policy	Cancelled	D-070809-S
Fostering Hope Research Project Shannon Dorsey, Ph.D.   University of Washington / Public Behavioral Health & Justice Policy	Approved	D-072909-S
Institutional Factors Impacting Latinos Experiences in the Child Welfare System: Perceptions of Caseworkers Antonio Garcia, M.S.W.   University of Washington / School of Social Work (graduate student)	Approved	D-092409-S
The Social Success Project Beverly Wilson, Ph.D.   Seattle Pacific University	Deferred	D-122809-S
Pathways to Reunification Pilot Program Shannon Dorsey, Ph.D.   UW School of Medicine	Approved	D-123109-S
Division of Alcohol and Substance Abuse		
<b>Evaluation of the PROMETA Protocol</b> Dennis Donovan, Ph.D.   University of Washington / Alcohol & Drug Abuse Institute	Approved	D-011209-S
Impact of Integrated COD Treatment on Chemical Dependency Treatment Outcomes Sherry Lipsky, Ph.D.   Harborview Medical Center	Approved	D-121009-S
Medical Assistance		
Patient Navigation Project Laurie Cawthon, M.D., M.P.H.   DSHS Research and Data Analysis	Approved	D-121009-S
Public Health Policy Decisions Related to the Social- Emotional Development of Young Children Susan Kline, M.N.   University of Washington / Department of Child and Family Nursing	Completed	D-020609-S

Rare Genomic Structural Variants in Schizophrenia Caitlin Rippey, B.S.   University of Washington	Approved	D-021909-S
The Genetics of Schizophrenia  Jon McClellan, M.D.   DSHS / Mental Health Division	Approved	D-052609-S
South King County Mental I liness and Spirituality Evaluation Elizabeth Gordon, J.D., M.Div.   Graduate Student	Approved	D-052809-S
Community Reentry of Persons with Severe Mental Illness from State Prisons  Joseph Morrissey, Ph.D.   University of North Carolina at Chapel Hill	Conditionally Approved	D-102209-S
Family Planning Decision Making in Women at High Risk for Substance Abuse Therese Grant, Ph.D.   University of Washington	Approved	D-102909-S
DEPARTMENT OF HEALTH	Status	Study #
Community and Family Health		
Flight Attendants Health Study Lynne Pinkerton, M.D., M.P.H.   NIOSH - CDC	Approved	D-011109-H
<b>Tuberculosis Among the Homeless in Washington State</b> Maija Anderson, R.N., B.S.N.   University of Washington / School of Nursing	Approved	D-012709-H
Washington State Early Hearing Loss Detection, Diagnosis, and Intervention (EHDDI) Program Evaluation  Mercy Mvundura, Ph.D.   DOH / Maternal & Child Health	Not Research	D-020909-H
Washington State Early Hearing Loss Detection, Diagnosis, and Intervention (EHDDI) Program Evaluation Mercy Mvundura, Ph.D.   DOH / Maternal & Child Health	Approved	D-022009-H
Project LAUNCH Amira El-Bastawissi, MBCHB, Ph.D.   DOH / Maternal & Child Health	Approved	D-032609-H
Medication Use in Pregnancy and Birth Outcomes Program Sascha Dublin, M.D., Ph.D.   Group Health Center for Health Studies	Approved	D-032709-H
Socioeconomic Status and Tuberculosis in Washington State Eyal Oren, M.S.   Public Health - Seattle & King County	Approved	D-041509-H
Supporting Objective and Informed Prostate Cancer Treatment Decision Making Steven Zeliadt, Ph.D.  VA Puget Sound Healthcare System	Approved	D-042409-H
Black Women's Health Study: A Follow-Up Study of Cancer and Other Illnesses Lynn Rosenberg, Sc.D.   Boston University	Cancelled	D-052709-H
Tuberculosis Mortality in the United States: Epidemiology & Prevention Opportunities Susan Buskin, Ph.D.   Public Health - Seattle & King County	Approved	D-090309-H
Evaluation of Plan Forward Diabetes Prevention Program in Community YMCA's  Marilyn Sitaker, M.P.H.   DOH / Chronic Disease Prevention Unit	Approved	D-090909-H
Healthy Youth Survey 2010 Lillian Bensley, Ph.D.   DOH / Non-Infectious Conditions	Approved	D-092309-H

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A Multi-State Study of Cancer Treatment and Outcomes Among American Indians Scott Ramsey, M.D., Ph.D.  Fred Hutchinson Cancer Research Center	Conditionally Approved	D-09509-H
National Immunization Survey - NIS-IIS Match Project Cynthia Howes, M.S.   DOH / MCH Assessment Section	Approved	D-100309-H
Interagency Record Match to Ascertain HIV-Positive Medicaid Recipients Not Reported in the HIV/AIDS Registry Tom Jaenicke, M.P.H., M.B.A., M.E.S.   DOH / Infectious Disease and Reproductive Health	Cancelled	D-101209-H
A Descriptive Analysis of Late HIV Diagnosis in Washington State Laura Saganic, B.S.   University of Washington (graduate student)	Approved	D-102009-H
Youth Development Pregnancy Prevention Program Study Carole Miller, M.Ed.   Planned Parenthood of the Great Northwest	Cancelled	D-111909-H
Epidemiology, Health Statistics, and Public Health Laboratories		
Comparative Assessment of Uniformed Service Family Pregnancy, Birth and Infant Outcomes in Washington State John Barrett, M.D., M.P.H.   Madigan Army Medical Center	Approved	D-011609-H
Newborn Screening Results Project: Key Informant Interviews with Parents, Physicians, and NBS Programs Sylvia Au, M.S.   Hawaii Department of Health	Approved	D-021309-H
Spinal Surgery for Metastatic Disease: Assessment of Utilization, Trends, & Costs Michael Lee, M.D.   University of Washington / Department of Orthopaedics & Sports Medicine  Perinatal Characteristics & Adult Ovarian & Circadian	Cancelled	D-040609-H
Function: Validation Study  Kathryn Adeney, M.P.H.   University of Washington (graduate student)	Approved	D-042309-H
Accuracy of Self-Reported Prenatal Smoking in Birth Records Beth Mueller, Dr.P.H.  Fred Hutchinson Cancer Research Center	Approved	D-050409-H
Diabetes Evaluation in Washington (DEW-IT) Study William Hagopian, M.D., Ph.D.  Pacific Northwest Diabetes Research Institute	Approved	D-052909-H
Northwest Tribal Registry and Seattle Indian Health Board Death and CHARS Record Linkages Victoria Warren-Mears, Ph.D.   Northwest Portland Area Indian Health Board	Approved	D-061809-H
Medication Use and Outcomes in Pregnancy David Smith, Ph.D., R.Ph.   Kaiser Permanente Center for Health Research	Approved	D-062309-H
BRFSS Pilot Health Study David Cantor, Ph.D.  Westat	Approved	D-062409-H
Behavioral Risk Factor Surveillance System (BRFSS) Katrina Wynkoop Simmons, Ph.D.   DOH / Center for Health Statistics	Cancelled	D-092909-H
Behavioral Risk Factor Surveillance System (BRFSS) Katrina Wynkoop Simmons, Ph.D.   DOH / Center for Health Statistics	Approved	D-110909-H

Evaluation of Tetravalent Meningococcal Conjugate Vaccine Effectiveness Chas DeBolt, R.N., M.P.H.   DOH / Communicable Disease Epidemiology	Approved	D-121509-H
Health Systems Quality Assurance		
Improving Pre-Hospital Trauma Triage Craig Newgard, M.D., M.P.H.   Oregon Health & Science University	Approved	D-031109-H
The Effect of Banning Prior Authorization for Emergency Services on Treatment Intensity and Health Outcomes Yaa Akosa Antwi, M.Phil.   Carnegie Mellon University	Cancelled	D-031109-H
DEPARTMENT OF LABOR AND INDUSTRIES	Status	Study #
Research and Data Services		
Vocational Rehabilitation Pilot Program Evaluation Jeanne Sears, Ph.D., M.S., R.N.   University of Washington /		
Department of Health Services	Approved	D-041709-L
20-Year Trends in Work-Related Injuries and Disorders Among Carpenters Hester Lipscomb, Ph.D.   Duke University Medical Center / Occupational & Environmental Medicine  Safety and Health Assessment and Research for Prevention (SHARP)	Approved	D-101509-L
Workplace Violence in Washington State Psychiatric Hospitals		
Nanette Yragui, Ph.D.   Labor & Industries / SHARP	Approved	D-012909-L
The Evaluation of the Physical Load of Four Lateral Patient Transfers Stephen Bao, Ph.D.   Labor & Industries / SHARP	Approved	D-021809-L
Renal Disease in a Cohort of Lead-Exposed Workers Kyle Steenland, Ph.D.   Emory University	Deferred	D-112509-L
Matching BLS Data to Workers Compensation Claims David Bonauto, M.D.   Labor & Industries / SHARP	Approved	D-120109-L
OTHER**	Status	Study #
CASA Program Evaluation (Charles) Dee Wilson, M.S.W.   University of Washington School of Social Work	Cancelled	D-010709-U
Male Family Planning Research Project David Fine, Ph.D.   Center for Health Training	Approved	D-081809-U
Cross-Site Survey Confidential Data Set Ann Glusker, Ph.D.   Public Health - Seattle & King County	Approved	D-111309-U
Medicaid Asthma Home Visit Project James Krieger, M.D., M.P.H.   Public Health - Seattle & King County	Cancelled	D-122209-U

 $<sup>{\</sup>color{red}^{**}} \textbf{Reviewed at the request of the researcher's home institution; not otherwise in WSIRB jurisdiction. } \\$ 

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#### 1945 **Nuremberg Trials** Medical experimentation abuses by Nazi doctors comes to public attention 1940 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 WWII modern research 1953 **NIH Requirement** · National institutes of Health requires that all proposed clinical research 1950 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 1966 1960 **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 1970 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 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 1980 Federal Register in 1979 Three general ethical principles provide a framework for human subjects 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 1991 1990 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" **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 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.

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History of Human Subjects Protection IN THE UNITED STATES



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** 

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