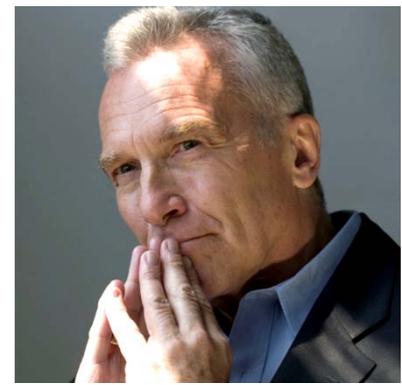




## ACTIVITY REPORT 2010: Washington State Institutional Review Board

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

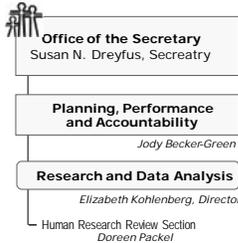
**August 2011**



# DSHS

WASHINGTON STATE  
**Department of Social  
and Health Services**

**Headquarters located at:**  
14<sup>th</sup> and Jefferson Street  
Olympia, WA 98504



## HRRS/WSIRB

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## Information About this Publication

**Title:** Washington State Institutional Review Board, January – December 2010

**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 2010. 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

**Geography:** Washington State

**Time Period:** January – December 2010

**Publication Date:** August 2011

**Publication Number:** 11.164

**Authors:** Maggie Frederick, Lilly Moneer, Doreen Packel

**Cover Design by:** DSHS Research and Data Analysis Division, photo courtesy of Microsoft (free domain)

## 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

August 2011

*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 2010. 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](mailto: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,



**Doreen Packel, M.P.A., C.I.P.**  
Human Protections Administrator  
Department of Social and Health Services

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## WASHINGTON STATE INSTITUTIONAL REVIEW BOARD

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### Chair

**Hanne Thiede**, D.V.M., M.P.H.  
Senior Epidemiologist  
Public Health – Seattle and King  
County

### Executive Secretary

**Michael A. Garrick**, Ph.D.  
Coordinator  
DSHS Human Research Review  
Section

### Associate Executive Secretary

**Margaret Frederick**, M.P.H., C.I.P.  
Review Coordinator  
DSHS Human Research Review  
Section

### Members

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**Kim Ambrose**, J.D.<sup>1</sup>  
Prisoner Representative

**Cindy Barchiesi**, Pharm.D.<sup>1</sup>  
Pharmacist  
DSHS Western State Hospital

**Stephanie Barton**, M.A.  
Manager  
DSHS Aging and Disability Services  
Administration

**David Bonauto**, M.D., M.P.H.  
Associate Medical Director – SHARP  
Department of Labor & Industries

**Kevin Campbell**, Dr.P.H.  
Research Investigator  
DSHS Aging and Disability Services  
Administration

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Section Manager and Lead  
Epidemiologist  
DOH Infectious Disease &  
Reproductive Health

**M. Patricia deHart**, Sc.D.  
Epidemiologist  
DOH Maternal and Child Health

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Illuminata, Inc.

**Robert M. Fineman**, M.D., Ph.D.  
Dean, Health & Human Services Div.  
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School of Social Work, University of  
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**Anna Y. Leon-Guerrero**, Ph.D.  
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Pacific Lutheran University

**Maureen Marcenko**, M.S.W., Ph.D.  
Associate Professor  
School of Social Work  
University of Washington

**Barbara Burns McGrath**, Ph.D.  
Research Associate Professor  
School of Nursing  
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**Robert D. Mootz**, D.C.<sup>2</sup>  
Associate Medical Director for  
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**Melanie Payne**, M.P.H.<sup>12</sup>  
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Clark County Health Department

**Katrina Wynkoop Simmons**, Ph.D.  
Coordinator – BRFS  
DOH Center for Health Statistics

**Dolf van den Heuvel**, Ph.D.  
Lead Psychologist  
DSHS Rainier School

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<sup>1</sup> Ad Hoc member

<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 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.

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.

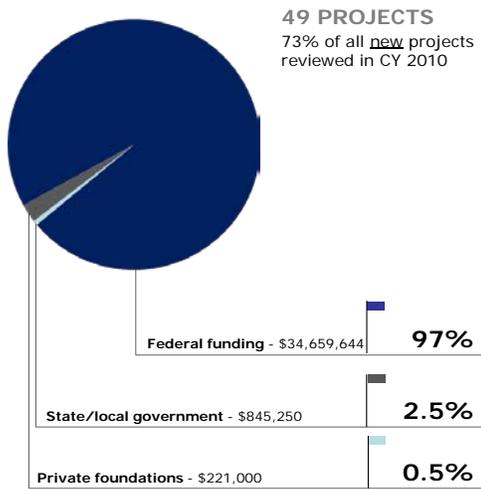
### Confidentiality of Materials

All Review Board materials 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 \$35,725,894



The chart to the left shows **the source of funding for new studies reviewed** in calendar year 2010. Among the 49 projects reviewed during 2010 that had been awarded project-specific funding, the vast majority were funded by various branches of the federal government. We expect that this dramatic increase in funding over the previous year is a result of the American Recovery and Reinvestment Act of 2009 (ARRA).

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, and public universities.

2010

**Goodbye and Best Wishes**

Mike Garrick retired in November 2010, starting this new phase in his life by spending several months in northern Thailand. We thank him for his dedication, leadership, and commitment to the work of the WSIRB. Go to the next page for an interesting overview of his years in human subject protections, in his "Retrospective" on more than two decades in this field.

**Distinguished Members:**

Two Review Board members -- Dr. Barbara Burns McGrath and Dr. Kevin Campbell -- marked 10 years serving on the WSIRB. As a token of appreciation for their dedication and continued service, each was provided with a WSIRB jacket and an engraved clock. Both individuals, who are now "Distinguished Members," will remain on the WSIRB.

**Applause for Academic Achievement**

Review Board member Annie Keeney completed her MSW at Eastern Washington University. Antonio Garcia completed his PhD in Social Welfare at the University of Washington.

**Moving on**

We are sad to note several Board members departing. Dr. Robert Fineman resigned from the Review Board in October. Dr. Fineman had demonstrated true dedication to human subjects protection over 16 years. Maria Courogen was

promoted to DOH Director of Infectious Disease & Reproductive Health. Ms. Courogen served on the WSIRB for 8 years. Review Board member Antonio Garcia resigned from the Review Board to accept a faculty position at San Diego State University. Stephanie Barton moved to Europe, where she will continue to pursue her PhD.

**Fiscal Belt-Tightening**

With the elimination of many state boards and commissions and the bleak economic forecast, the Review Section faced restrictions on meeting expenses and travel. WSIRB members are no longer reimbursed for mileage; airfare for members who live in Eastern Washington is no longer feasible. Some WSIRB members are now patched into the meeting via Skype or telephone conference. We explored the possibility of holding video-conferences at four DSHS offices to reduce travel expenses. However, this option is not feasible, as arrangements could be canceled at anytime if a higher level government official wished to use the facility.

Review Section staff now bring coffee and home-baked treats to meetings. Given the nature of human subjects review, it is important to keep WSIRB members connected and actively involved in the process. We will continue to explore ways to cut costs while ensuring that we accomplish our important mission to protect human subjects.

**Out and About**

Review Coordinator Maggie Frederick gave a presentation on research with vulnerable populations at Pacific Lutheran University. The research methods course, taught by fellow WSIRB member Dr. Anna Leon-Guerrero, is primarily for social work students. Maggie Frederick and Lilly Moneer gave a presentation at L&I/SHARP about the Review Board, jurisdiction, what requires review, etc. in the Fall. SHARP has seen an increase in federal grants and increased professional staff in the past few years.

**Contacts with Local IRBs**

Eight Fellows participating in a Western IRB/World Health Organization program to improve human subject protections in other countries attended WSIRB meetings during 2010. Western IRB attendees were Jim Baldwin, Regulatory Analyst, and Sue Middle, WHO Fellows Program Coordinator. The WHO Fellows hailed from Korea, Thailand, Brazil, and China. Fellows are usually health care professionals or IRB members in their home countries.



**Michael A. Garrick, Ph.D.** served as Executive Secretary of the Washington State Institutional Review Board from April 1986 until his retirement in November 2010

Looking back over this nearly 25 year period it's not surprising that many things have changed. The number of research projects reviewed per year nearly tripled during the first half of this period, from 88 in 1986 to 275 in 1997. When my tenure started, a half time secretary helped me with the review load; when I left the Review Section, we had a professional staff totaling 2.75 FTEs.

Significant structural changes in both the Review Board and the agencies the Review Board serves occurred over the years. From a single committee serving a single agency in 1986, the WSIRB expanded to two committees serving four state agencies, as well as performing reviews for research conducted in four local health jurisdictions. Reflecting efforts to use public resources more efficiently and to provide review services to a larger and more diverse group of organizations, in 2002 the official name of the IRB was changed from the DSHS/DOH Human Research Review Board to the Washington State Institutional Review Board. Taking advantage of increased operational efficiencies produced by a series of continuous quality improvement initiatives, in 2008 the WSIRB was re-constituted into a single committee that now meets monthly rather than eight times per year.

Two major transformations affected WSIRB operations during the past two decades. Both have resulted in significant improvements in efficiency. The first was stimulated by the technological transformation that revolutionized the modern workplace over the past quarter century. For the Review Board, advances in electronic technology facilitated an almost complete transformation from a manual, paper-based review system to an automated, electronic and Internet-based system. During the first half of my tenure, the Review Section mailed massive Research Application Kits to prospective applicants who contacted us primarily by telephone.

Completed applications (18 to 20 copies) were mailed to the Review Section and distributed to Review Board members; Board decisions were mailed back to investigators in the form of a letter sent by U.S. Mail. The Review Section manually updated a "Status Review Board" on the wall of our office by sliding type-written tabs into slots on the board; such was our "database." The second major transformation in WSIRB operations resulted from a Continuous Quality Improvement Initiative that the Review Section launched in the early part of the last decade. Some of the initiatives adopted from this effort are:

- WSIRB Rules of Order, adapted from Robert's Rules in Plain English, focused review deliberations, encouraged broader participation, and increased efficient use of time during full committee meetings
- Administrative pre-review of all applications identified potential issues that could be addressed prior to committee meetings, thereby decreasing the number of applications deferred during initial review
- A totally redesigned application form facilitated submission of all the information needed for review while minimizing the submission of unnecessary information
- Continuous training in the protection of human research subjects for Review Section staff, WSIRB members, and researchers, through In-Service training during meetings and on-line CITI training
- Periodic customer surveys of researchers as well as program managers in the state agencies collect information about what's working well and what operational areas could be improved.

These efforts continue as the Review Section strives to continuously improve operations in support of the core mission of WSIRB to protect the rights and welfare of human subjects while ensuring that risks to subject have been minimized. I take satisfaction in believing I made some contributions toward supporting this mission during my tenure and that these efforts will continue into the future.

## ASK THE IRB



***I am a DSHS/DOH/L&I employee. Do I need WSIRB review for internal agency-sponsored 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*, 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?***

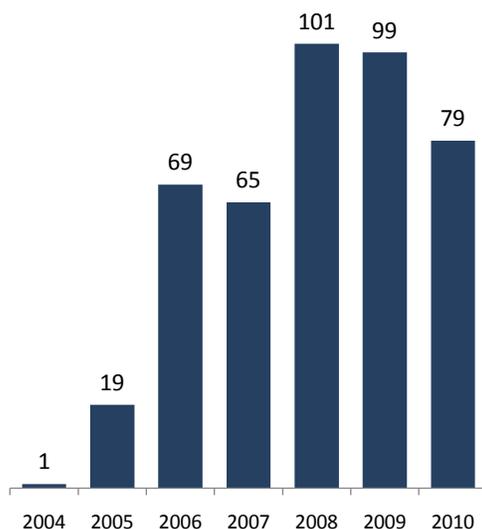
It may. If a demonstration program will be implemented on a pilot basis to a limited pool of clients or limited geographic area, the evaluation of the pilot program may require WSIRB review. In general, evaluations of pilot programs or demonstration projects are considered *research*.

***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 not 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:

- 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 general, 10% of Requests are determined to be research that is *not* exempt.

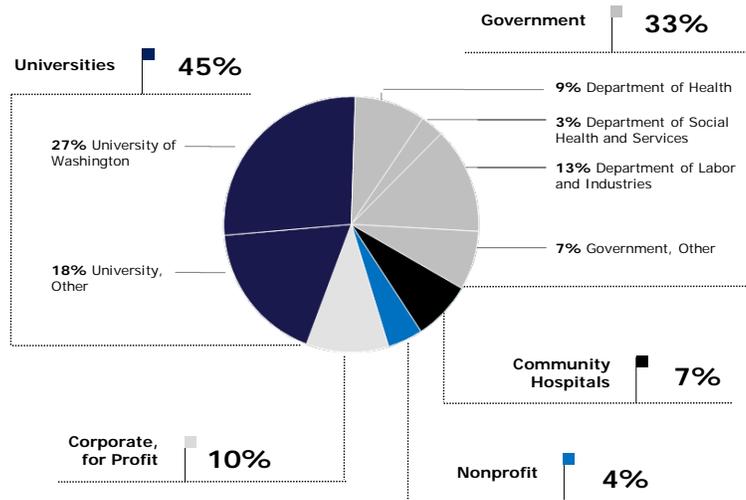
Review Section staff cannot determine exemption retroactively; all Requests must be submitted **before** an activity has been started.

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

## APPLICATIONS REVIEWED IN 2010

### RESEARCHER AFFILIATION

January – December 2010 | Proposals Reviewed: 67



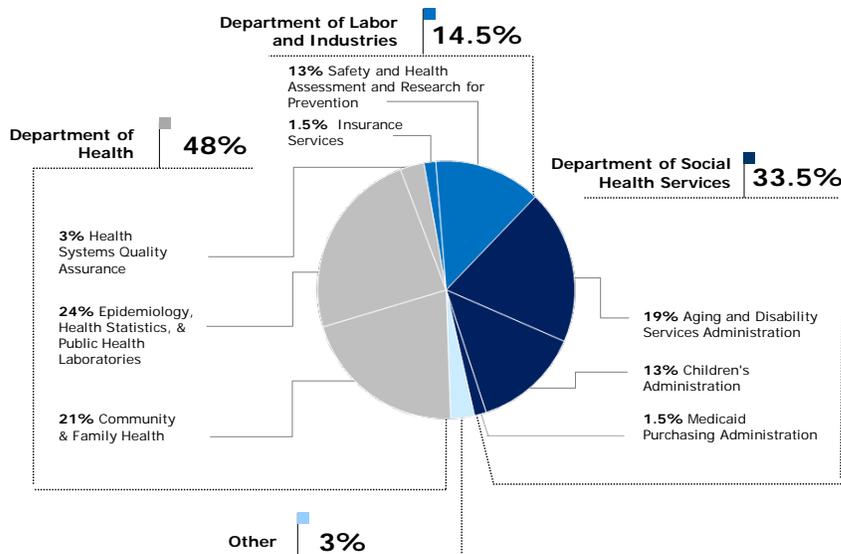
### RESEARCHER AFFILIATION:

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

Source: WSIRB Dec 31, 2010

### AGENCY PROGRAM

January- December 2010 | Proposals reviewed: 67



### AGENCY PROGRAM:

The Department of Social and Health Services and Department of Health together accounted for 81.5% and Department of Labor and Industries had 14.5% of all the new proposals reviewed during 2010.

Note: DSHS was reorganized in 2010. The data presented here show the Administrations involved, rather than the smaller divisions and programs within an Administration that were reported in previous years.

Source: WSIRB Dec 31, 2010

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.

## ACTIVITY REPORT, JANUARY - DECEMBER 2010

The following research applications were submitted for WSIRB review from January through December 2010. 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 2010. 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 #
<b><u>Aging and Disability Services Administration</u></b>		
<b>A Preliminary Evaluation of Multi-Family Group Treatment for Use with Children Diagnosed with Mental Illness</b> L. Lee Carlisle, M.D.   DSHS Child Study and Treatment Center	Approved	D-011910-S
<b>Evaluating Juvenile Adjudicative Competence with a Semi-Structured Interview</b> Frances Lexcen, Ph.D.   DSHS Child Study and Treatment Center	Approved	D-021710-S
<b>Enhance Mobility Program Study</b> Rebecca Logsdon, Ph.D.   University of Washington	Approved	D-022310-S
<b>Evaluation of the Treatment Mall at Eastern State Hospital</b> Robert Short, Ph.D. Washington Institute for Mental Health Research and Training   Washington State University, Spokane	Approved	D-022510-S
<b>Cognitive Behavioral Therapy for Psychosis Pilot Study</b> Eric Strachan, Ph.D.   University of Washington Dept of Psychiatry & Behavioral Sciences	Approved	D-022610-S
<b>The Parent-Child Assistance Program (PCAP)</b> Therese Grant, Ph.D. University of Washington School of Medicine	Approved	D-030310-S
<b>Residential vs. Intensive Outpatient Prison-Based Treatment (The NOBLE Study)</b> William Burdon, Ph.D.   University of California - Los Angeles	Approved	D-031610-S
<b>Behavioral Reinforcement to Increase Treatment Engagement (Project BRITE)</b> William Burdon, Ph.D.   University of California - Los Angeles	Approved	D-031710-S
<b>Incentives and Alerts for Improving Performance in Washington State</b> Deborah Garnick, Sc.D.   Brandeis University	Pre-reviewed	D-082410-S
<b>PEARLS Dissemination Study -- Administrative Records</b> Mark Snowden, M.D. University of Washington   Health Promotion Research Center	Approved	D-090910-S
<b>Effectiveness of Housing First For Non-Chronically Homeless Individuals Who Are High Utilizers Of Inpatient Psychiatric Treatment</b> Molly Brown, M.A.   DePaul University (student)	Deferred	D-100110-S
<b>Expanding and Enhancing Spokane County's Therapeutic Drug Court</b> Robert Short, Ph.D. Washington Institute for Mental Health Research and Training   Washington State University, Spokane	Approved	D-101710-S
<b>Evaluation of Western State Hospital's Tobacco Dependence Training Program</b> Jennifer Stuber, Ph.D. University of Washington School of Social Work	Approved	D-122410-S

**Children’s Administration**

<b>Reunification and Permanency Project</b> Mark Courtney, Ph.D. University of Washington   Partners for our Children	Approved	D-021610-S
<b>Preventing Child Abuse and Neglect through Nurse Home Visitation</b> Vickie Ybarra, M.P.H.  Yakima Valley Farm Workers Clinic	Cancelled	D-062810-H
<b>Understanding Healthy Relationships</b> Kym Ahrens, M.D., M.P.H. Seattle Children’s Hospital   Seattle Children’s Research Institute	Approved	D-072810-S
<b>Raising Awareness of Problem Gambling with Child Welfare Workers</b> Blake Beecher, Ph.D.  Eastern Washington University	Approved	D-080210-S
<b>Family Violence in Washington State</b> Thomas George, Ph.D.  Administrative Office of the Courts	Deferred	D-101210-S
<b>Retrospective Collection of Child Protective Service Reports among National Early Head Start Research &amp; Evaluation Project Participants</b> Beth Green, Ph.D.  Portland State University	Deferred	D-101310-S
<b>Brain &amp; Behavior in Children</b> Andrew Meltzoff, Ph.D. University of Washington   Institute for Learning and Brain Sciences	Conditionally Approved	D-102910-S
<b>Evaluation of the Yakima Valley System of Care</b> Eric Bruns, Ph.D   University of Washington   Dept of Psychiatry & Behavioral Sciences	Approved	D-103110-S
<b>Feasibility of Substance Abuse Prevention in Foster Care Settings</b> Kevin Haggerty, Ph.D. University of Washington   Social Development Research Group	Pre-reviewed	D-110110-S

**Medicaid Purchasing Administration**

<b>Advancing Innovative &amp; Comparative Effectiveness Research in Cancer Diagnostics (ADVICE): Breast Cancer Study</b> Scott Ramsey, M.D., Ph.D.  Fred Hutchinson Cancer Research Center	Conditionally Approved	D-121010-S
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**DEPARTMENT OF HEALTH** Status Study #

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**Community and Family Health**

<b>HIV-Positive Medicaid Recipients not Reported to HIV/AIDS Disease Registry</b> Tom Jaenicke, M.P.H., M.B.A., M.E.S. DOH Infectious Disease and Reproductive Health	Approved	D-010710-H
<b>Washington Pregnancy Risk Assessment Monitoring System (PRAMS)</b> Amira El-Bastawissi, Ph.D. DOH Maternal & Child Health Assessment	Approved	D-012710-H
<b>Analysis of Sudden Unexpected Infant Deaths during the Implementation of a Crib Distribution Program</b> Rachel Moon, M.D.  Children’s National Medical Center	Approved	D-021010-H
<b>The Primordial Prevention of Overweight In American Indian Children (PTOTS): WIC Data Comparison</b> Njeri Karanja, Ph.D. Kaiser Permanente Center for Health Research	Approved	D-031210-H

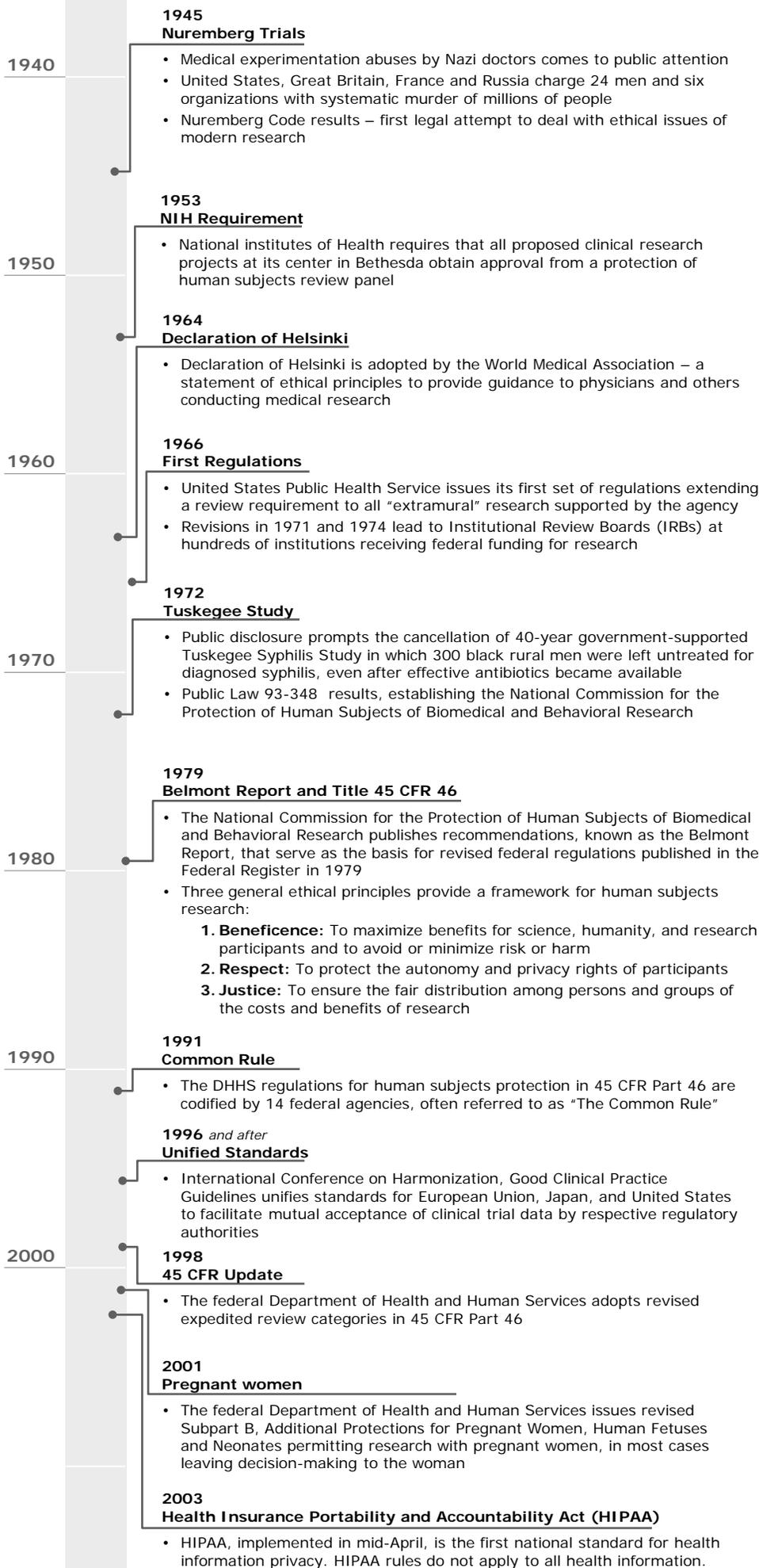
<b>Pacific Northwest Health Assessment in LGBTQ Community</b> Nguyet Tran, M.P.H. DOH Tobacco Prevention & Control Program	Cancelled	D-032510-H
<b>Molecular Epidemiology of Lung Cancer</b> Chu Chen, Ph.D.  Fred Hutchinson Cancer Research Center	Approved	D-040910-H
<b>Building Community Collaboration to Increase WIC Clients' Fruit and Vegetable Consumption</b> Donna Johnson, Ph.D. University of Washington Nutritional Sciences	Approved	D-051310-H
<b>A Multi-State Study of Cancer Treatment and Outcomes among American Indians</b> Scott Ramsey, M.D., Ph.D. Fred Hutchinson Cancer Research Center	Approved	D-070810-H
<b>Pregnancy Factors and Breast Cancer</b> Beth Mueller, Dr.P.H.  Fred Hutchinson Cancer Research Center	Approved	D-071910-H
<b>A Study of Cancer among United States Firefighters</b> Travis Kubale, Ph.D. National Institute for Occupational Safety & Health	Conditionally Approved	D-082310-H
<b>Tracking Disparities in the Effective Delivery of Health Services</b> Christopher Murray, M.D, D.Phil. University of Washington	Approved	D-082710-H
<b>National HIV Behavioral Surveillance (NHBS)</b> Hanne Thiede, D.V.M., M.P.H. Public Health Seattle & King County	Conditionally Approved	D-121510-H
<b>Study of Melanoma Incidence Rates in Whatcom County</b> Victor Chan, Ph.D.   Western Washington University	Deferred	D-122110-H
<b>Washington State Project LAUNCH Services Outcome Evaluation</b> Amira El-Bastawissi, Ph.D. DOH Maternal & Child Health Assessment	Conditionally Approved	D-123010-H
<b><u>Epidemiology, Health Statistics, and Public Health Laboratories</u></b>		
<b>Washington Environmental Biomonitoring Survey (WEBS)</b> Juliet VanEenwyk, Ph.D. DOH  Epidemiology, Health Statistics, & Public Health Laboratories	Approved	D-012610-H
<b>Need for Follow-Up Imaging after Grade 3 Renal Injury</b> Bryan Voelzke, M.D. Harborview Medical Center	Approved	D-020110-H
<b>The Geographic Distribution of Optic Nerve Hypoplasia</b> Mark Borchert, M.D. The Vision Center at Children's Hospital Los Angeles	Approved	D-020310-H
<b>Coded Emergency Department Data System (CEDDS)</b> Wendy Shultis, Ph.D. DOH Center for Health Statistics	Approved	D-021210-H
<b>Confronting Climate Change Health Risks in the Pacific Northwest</b> Richard Fenske, Ph.D. University of Washington Environmental & Occupational Health Sciences	Approved	D-031110-H
<b>Trends in Congenital Hypothyroidism in Washington State</b> Angela Badaru, M.D. Seattle Children's Hospital	Cancelled	D-040110-H

<b>Trends in Congenital Hypothyroidism in Washington State</b> Angela Badaru, M.D. Seattle Children's Hospital	Cancelled	D-050110-H
<b>Communities Putting Prevention to Work: Supplement to the Behavioral Risk Factor Surveillance System (CPPW-BRFSS)</b> Nadine Chan, Ph.D. Public Health Seattle & King County	Approved	D-052910-H
<b>Cardiac Arrest Blood Study Repository (CABS-R)</b> David Siscovick, M.D., M.P.H. University of Washington Cardiovascular Health Research Unit	Approved	D-080510-H
<b>University of Washington Twin Registry Fetal Origins Project</b> Eric Strachan, Ph.D. University of Washington Dept of Psychiatry & Behavioral Sciences	Cancelled	D-072010-H
<b>The Environmental Determinants of Diabetes in the Young (TEDDY) Study</b> William Hagopian, M.D., Ph.D. Pacific Northwest Diabetes Research Institute	Approved	D-082610-H
<b>Infants Born to Pregnant Women with Confirmed or Suspected 2009 H1N1 Influenza</b> Sonja Rasmussen, M.D. Centers for Disease Control and Prevention	Approved	D-100410-H
<b>Optimal Newborn Screening for Cystic Fibrosis using the Immunoreactive Trypsinogen Test</b> John Klaassen Whitman College (student)	Conditionally Approved	D-102810-H
<b>VLCAD Newborn Screening &amp; Follow-Up Collaborative Investigation</b> J. Lawrence Merritt, II, M.D. Seattle Children's Hospital	Cancelled	D-110310-H
<b>Trends in Congenital Hypothyroidism in Washington State</b> Angela Badaru, M.D. Seattle Children's Hospital	Cancelled	D-110410-H
<b>Maternal Smoking and Risk of Juvenile Idiopathic Arthritis</b> Susan Shenoj, M.D. Seattle Children's Hospital	Conditionally Approved	D-120710-H
<b><u>Health Systems Quality Assurance</u></b>		
<b>Long Term Survival in Geriatric Trauma Patients</b> Giana Hystad Davidson, M.D. Harborview Injury Prevention & Research Center	Approved	D-010410-H
<b>Use of the Washington State Trauma Registry for Occupational Injury Surveillance</b> Jeanne Sears, Ph.D., M.S., R.N. University of Washington Department of Health Services	Approved	D-070110-H

DEPARTMENT OF LABOR AND INDUSTRIES	Status	Study #
<b><u>Insurance Services</u></b>		
<b>Work-Related Risks of Certified Athletic Trainers</b> Kristen Kucera, Ph.D., A.T.C., L.A.T. Duke University Medical Center Dept of Occupational & Environmental Medicine	Conditionally Approved	D-092910-L
<b><u>Safety and Health Assessment and Research for Prevention (SHARP)</u></b>		
<b>Incivility Study</b> Nanette Yragui, Ph.D. Department of Labor & Industries   SHARP	Cancelled	D-020210-L
<b>Bullying Among Library Staff: Work, Family, and Health Outcomes</b> Nanette Yragui, Ph.D. Department of Labor & Industries   SHARP	Approved	D-020510-L
<b>Using Workers' Compensation Data to Identify High Risk Workplaces for Work-Related Musculoskeletal Disorders</b> Barbara Silverstein, Ph.D., M.P.H. Department of Labor & Industries   SHARP	Approved	D-042910-L
<b>Injury Reduction among Temporary Workers in Washington State through Surveillance</b> David Bonauto, M.D., M.P.H. Department of Labor & Industries   SHARP	Approved	D-043010-L
<b>Minor &amp; Young Worker Occupational Injury Surveillance Plan</b> Eric Jalonen, M.P.H. Department of Labor & Industries   SHARP	Approved	D-052810-L
<b>In the Bag, Improving Coffee Harvesting for Workers in Nicaragua</b> Barbara Silverstein, Ph.D. Department of Labor & Industries   SHARP	Approved	D-092810-L
<b>Trucking Injury Reduction Emphasis through Surveillance (TIRES)</b> Caroline Smith, M.P.H. Department of Labor & Industries   SHARP	Approved	D-093010-L
<b>Workplace Violence in Washington State Hospital Emergency Departments</b> Nanette Yragui, Ph.D. Department of Labor & Industries   SHARP	Cancelled	D-100210-L
<b>Workplace Violence Prevention in Washington State Hospital Emergency Departments</b> Nanette Yragui, Ph.D. Department of Labor & Industries   SHARP	Pending	D-122610-L
<b>OTHER**</b>	<b>Status</b>	<b>Study #</b>
<b>The Sustainable Prisons Project</b> Nalini Nadkarni, Ph.D. The Evergreen State College	Deferred	D-112210-U
<b>King County Recovery Oriented System of Care (ROSC) for Pregnant and Parenting Women</b> James Vollendroff, M.P.A. King County Mental Health Chemical Abuse and Dependency Services Division	Conditionally Approved	D-122310-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



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:  
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DSHS Human Research Review Section website:  
**[www.dshs.wa.gov/rda/hrrs](http://www.dshs.wa.gov/rda/hrrs)**