



MARCH 2008

ACTIVITY REPORT

Washington State Institutional Review Board

July 2006-December 2007



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







DSHS

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Information About this Publication

Title: Washington State Institutional Review Board, July 2006-December 2007

Abstract: This report provides an overview of the Washington State Institutional Review Board, formerly known as the DSHS/DOH Human Research Review Board. It summarizes the Board's authority and functions, outlines the human research review process, and describes major activities during July 2006 to December 2007. 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.

Category: Institutional Review Board Activities

Geography: Washington State

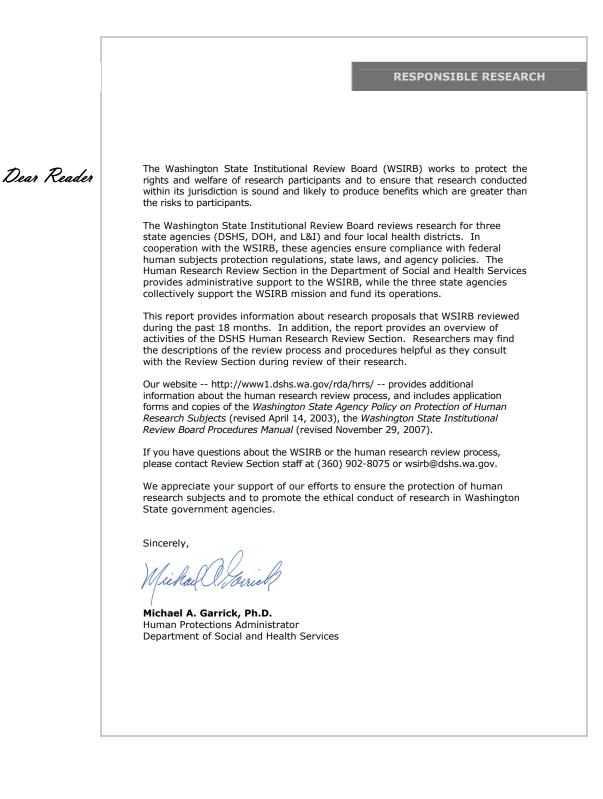
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WASHINGTON STATE INSTITUTIONAL REVIEW BOARD A

Chair Dennis McBride, Ph.D. Senior Research Associate Washington Institute, Western Branch **Executive Secretary Michael A. Garrick**, Ph.D. Coordinator DSHS Human Research Review Section

Associate Executive Secretary Margaret Frederick, M.P.H., C.I.P.

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Robert D. Mootz, D.C. Associate Medical Director for Chiropractic Department of Labor & Industries

Melanie Payne, M.P.H. Epidemiologist Clark County Health Department

Nancy Osborne Sclater Principal Pinkerton Brown, LLC

REVIEW BOARD ORGANIZATION AND MEMBERSHIP

Composition of the Review Board

The Washington State Institutional Review Board consists of two separate, parallel Review Boards: Board A and Board B. Each Review Board has 14 to 16 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.

WASHINGTON STATE INSTITUTIONAL REVIEW BOARD B

Robert M. Fineman, M.D., Ph.D. Medical Consultant DOH Newborn Screening Program	Executive Secretary Michael A. Garrick , Ph.D. Coordinator DSHS Human Research Review Section
Members	Associate Executive Secretary Margaret Frederick, M.P.H., C.I.P. Review Coordinator DSHS Human Research Review Section
Kim Ambrose, J.D.	Katrina Wynkoop Simmons, Ph.D.
Prisoner Representative	Coordinator – BRFSS
Cindy Bouillon-Jensen, M.A.,	DOH Center for Health Statistics
C.I.P.	John Steiger, Ph.D.
Consultant	Senior Forecaster
Human Subjects Protections	Caseload Forecast Council
Kevin Campbell, Dr.P.H. Research Investigator DSHS Division of Alcohol and Substance Abuse	Hanne Thiede, D.V.M., M.P.H. Senior Epidemiologist Public Health – Seattle and King County
Substance Abuse	county
Maria Courogen, M.P.H. Section Manager and Lead Epidemiologist DOH Infectious Disease &	Dolf van den Heuvel, Ph.D. Lead Psychologist DSHS Rainier School
Reproductive Health	Ronald Williams, M.D., M.P.H. Medical Director
Barbara Burns McGrath, Ph.D. Research Associate Professor School of Nursing University of Washington	Yavapai County Detention Center
Lynne Clemmons Morris, M.S.W., Ph.D. Associate Professor, Social Work	

Duties

The Review Boards meet eight times per year at alternating six and seven week intervals. Board members are expected to attend at least five meetings per year. Depending on the workload, members spend approximately four to eight 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

Eastern Washington University

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 on which the proposal is being considered.

For more information see: Washington State Institutional Review Board Procedures Manual: http://www1.dshs.wa.gov/rda/hrrs/publ.shtm

2006

Quality Improvement Activities

The new research application became mandatory for all submissions to the WSIRB in July 2006. Proposals submitted on the old form are not accepted.

DSHS Human Research Review Section staff assessed the feasibility of paperless transmission of review materials and a password-protected website that WSIRB members would be able to access to obtain materials for review.

WSIRB Membership

Martha Holliday, M.P.H., achieved Distinguished Member status after serving 10 years on the Review Board

The WSIRB welcomed new members: Craig Woodworth, a non-scientist ("community") member; Maureen Marcenko, Ph.D., of the University of Washington School of Social Work; and Samantha Barker, M.S.W., DSHS Aging and Disability Services. Ron Williams, M.D., Medical Director, Juvenile Rehabilitation Administration, changed to ad hoc membership after he accepted a position in correctional health in Arizona.

Human Subjects Protection Conferences

WSIRB members Michael Garrick and Cindy Bouillon-Jensen attended the national conference sponsored by Public Responsibility in Research and Medicine (PRIM&R) in Washington, D.C.

2007

Quality Improvement Activities

IRB Authorization Agreements (IAA) were established to streamline workload and reduce redundant reviews. IAAs permit an institution to rely on another institution's IRB for review of research that is in the jurisdiction of both institutions. IAAs are in place with the University of Washington, Fred Hutchinson Cancer Research Center, Children's Hospital and Regional Medical Center, Washington State University, and Eastern Washington University.

Review Section staff began preliminary planning to consolidate both Review Boards. WSIRB meeting dates would change in frequency, to 10 meetings per year.

Consultant and Review Board member Cindy-Bouillon Jensen began to develop a training agenda and modules for veteran and new WSIRB members. Inservice training will occur at each Review Board meeting beginning in 2008.

Review Section staff member Maggie Frederick conducted four presentations for MSW candidates in the School of Social Work at Eastern Washington University. She focused on human subjects issues, the role of the WSIRB, and requirements for exemption.

The Review Section conducted a brief survey of Children's Administration Area Managers, to gauge their familiarity with the IRB and how to find information regarding the human subjects review process.

The Review Section also surveyed WSIRB members to gain an understanding of priority areas for ongoing in-service training on human subjects protection issues.

WSIRB membership

Steve Bowman, Ph.D., DOH Emergency Medical Service and Trauma Prevention, resigned from the WSIRB to accept a research faculty position at the University of Arkansas Medical Center.

Craig Woodworth resigned from the Board after one year of service, in order to pursue graduate studies in clinical psychology in Chicago.

Contacts with Local IRBs:

David Forster, J.D., C.I.P. Vice President for Regulatory Affairs at Western IRB, attended the March 2007 meeting to observe WSIRB functions, along with five foreign health professionals who came to Olympia for six months as part of the Western IRB/World Health Organization Fellows Program.

Another group of six Fellows observed the October 2007 WSIRB meeting, along with Bradley E. Waite, D.O., staff physician and Board member at Western IRB.

Two staff from the University of Washington Human Subjects Division observed a WSIRB meeting. Jean Lanz, Ph.D., is administrator of Committee J, which reviews social and behavioral research, and Shannon Sewards is the Assistant Director of Operations.

Review Section staff observed a meeting of the social and behavioral research committee at the University of Washington. In the fall, they observed a meeting at Western Institutional Review Board, a commercial IRB that has operated in Olympia since 1968.

Human Subjects Protection Conferences

Four WSIRB members attended a two-day conference on human subjects issues in social and behavioral research. The conference was sponsored by PRIM&R.



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 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
- Agency employees as investigator(s)

Washington State Agency Policy on the Protection of Human Research Subjects is more inclusive than the federal regulations for human subjects protection, in that all research involving human subjects is covered, regardless of the funding source. Federal regulations only apply to research funded all or in part by federal dollars.

FEDERAL REGULATIONS

- 42 CFR Part 2 Confidentiality of Alcohol and Drug Abuse Patient Records
- 45 CFR Part 46 Protection of Human Subjects
- 45 CFR Part 160 HIPAA General Administrative Requirements
- 45 CFR Part 164 HIPAA Privacy Rule

STATE

Revised Code of Washington:

- RCW 26.44 Abuse of Children
- RCW 42.48 Release of Records for Research
- RCW 70.02 Medical Records, Health Care Information Access and Disclosure
- RCW 70.124 Abuse of Patients
- RCW 74.34 Abuse of Vulnerable Adults

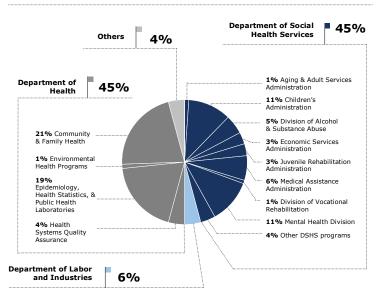
Washington Administrative Code: WAC 246-101 – Notifiable Conditions

STATE AGENCIES

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

AGENCY PROGRAM

July 2006-December 2007 | Proposals reviewed: 80



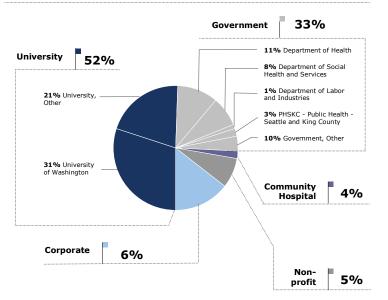
BY PROGRAM:

The Department of Social and Health Services and Department of Health accounted each for 45% and Department of Labor and Industries had 6% of all the incoming new proposals reviewed during July 2006-December 2007 to the WSIRB.

Source: WSIRB Dec 31, 2007

RESEARCHER AFFILIATION

July 2006-December 2007 | Proposals reviewed: 80



RESEARCHER AFFILIATION:

45% of the principal investigators were universitybased, with the University of Washington accounting for the large majority. The other 55% of researchers were affiliated with Government, Corporate, Community Hospitals, and Nonprofit.

Source: WSIRB Dec 31, 2007

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 from which the proposal was submitted. 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 "Unaffiliated"; 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 academic 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, JULY 2006-DECEMBER 2007

The following research applications were submitted for WSIRB review from July 2006 through December 2007. They are categorized by the program area in which the research will occur or the source of research subjects (see page 5 of this Report for an explanation). The "status" code indicates each application's status at the end of 2007. 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. Projects coded as "exempt" were submitted for WSIRB review, but were determined to be exempt from the requirement for human subjects review.

DEPARTMENT OF SOCIAL AND HEALTH SERVICES	Status	Study #
Aging and Disability Services Administration		
Efficacy of Antiepileptic Drug Combination Therapy in Patients with Refractory Epilepsy Nicholas Poolos M.D., Ph.D. Department of Neurology & Regional Epilepsy Center / University of Washington Children's Administration	Approved	B-082707-S
Educational Attainment of Foster Youth: Updated Achievement and Graduation Outcomes for Children in State Care Mason Burley M.P.A. Washington State Institute for Public Policy	Approved	A-020807-S
Foster Care to College Partnership: Evaluating Postsecondary Outcomes for Foster Youth	Concelled	
Mason Burley M.P.A. Washington State Institute for Public Policy	Cancelled	B-022607-S
Transitions to Adulthood: Outcomes in the Continuing Foster Care Program		
Laura Schrager M.A. Washington State Institute for Public Policy	Approved	A-031307-S
Infant Mental Health Dependency Court Project Sheri Hill Ph.D. UW / Center on Infant Mental Health & Development	Cancelled	B-032707-S
	Cancelleu	D-032707-3
King County Family Courts Study Eric Trupin Ph.D. UW / School of Medicine	Approved	B-050807-S
PETP Dependency Court Evaluations on the Psychosocial Outcomes for Dependency Cases Lisa Ferrari M.A. Antioch University / graduate student	Cancelled	B-053007-S
Skagit County Dependency Evaluation - Outcome Study Andrew Benjamin Ph.D. Antioch University Seattle & UW	Approved	B-080607-S
Foster Care Mental Health Consultation Pilot Eric Trupin Ph.D. UW / School of Medicine	Approved	A-091907-S
Does Hope Moderate the Relationship Between Attachment		
and Behavioral Outcomes in Foster Children? Lauren Shepherd M.A. Seattle Pacific University (graduate student)	Pending	A-110707-S
Division of Alcohol and Substance Abuse		
Evaluation of SeaMar Renacer Youth Treatment Program Eric Trupin Ph.D. University of Washington	Approved	B-072606-S
Drug Treatment Completion & Retention Throughout		
Washington Caleb Banta-Green M.P.H., M.S.W. UW / School of Public Health (doctoral student)	Approved	B-092506-S
King County Superior Court Reclaiming Futures Local		
Evaluation Peter Selby Ph.D. TriWest Group	Approved	B-120606-S

RCT Evaluating Improvement Strategies in Addiction Treatment David Gustafson Ph.D. University of Wisconsin / College of Engineering Division of Vocational Rehabilitation	Approved	B-051407-S
WorkStrides Elizabeth Swett Ph.D. Western Washington University / Continuing Education in Rehabilitation	Approved	A-072706-S
Economic Services Administration		
Workforce Training Results: Vocational Rehabilitation and WorkFirst Participants Carl Wolfhagen, M.P.A. Workforce Training & Education Coordinating Board	Exempt	A-062707-S
TANF Depression Study Marna Miller Ph.D. Washington State Institute for Public Policy	Conditionally Approved	B-092007-S
Juvenile Rehabilitation Administration		
Validation of the Self-Harm & Suicidal Behavior Screen for JRA Youth: Pilot Work André Ivanoff Ph.D. Columbia University/School of Social Work	Approved	B-032907-S
Students beyond Risk: Incarcerated Youth's Perspectives on Education Rachel Phillips, M.A., M.A.T. UW / College of Education (graduate student)	Pending	D-122007-S
Medical Assistance		
Exposure to Psychotropic Medications and Adverse Outcomes Dimitri Christakis M.D., M.P.H. UW / Child Health Institute	Cancelled	A-071406-S
Exposure to Psychotropic Medications and Adverse Outcomes	Cancelled Completed	A-071406-S A-092406-S
Exposure to Psychotropic Medications and Adverse Outcomes Dimitri Christakis M.D., M.P.H. UW / Child Health Institute The Year Following Myocardial Infarction: Patterns of Secondary Prevention in Washington James LoGerfo M.D., M.P.H. UW / Health Promotion Research		
Exposure to Psychotropic Medications and Adverse Outcomes Dimitri Christakis M.D., M.P.H. UW / Child Health Institute The Year Following Myocardial Infarction: Patterns of Secondary Prevention in Washington James LoGerfo M.D., M.P.H. UW / Health Promotion Research Center Cost Effectiveness of Patient Review and Restriction	Completed	A-092406-S
 Exposure to Psychotropic Medications and Adverse Outcomes Dimitri Christakis M.D., M.P.H. UW / Child Health Institute The Year Following Myocardial Infarction: Patterns of Secondary Prevention in Washington James LoGerfo M.D., M.P.H. UW / Health Promotion Research Center Cost Effectiveness of Patient Review and Restriction Wei Yen Ph.D. DSHS Health & Recovery Services Administration Do Medical Homes Improve Health Care Quality for Children with Special Health Care Needs? 	Completed Approved Conditionally	A-092406-S B-070307-S
 Exposure to Psychotropic Medications and Adverse Outcomes Dimitri Christakis M.D., M.P.H. UW / Child Health Institute The Year Following Myocardial Infarction: Patterns of Secondary Prevention in Washington James LoGerfo M.D., M.P.H. UW / Health Promotion Research Center Cost Effectiveness of Patient Review and Restriction Wei Yen Ph.D. DSHS Health & Recovery Services Administration Do Medical Homes Improve Health Care Quality for Children with Special Health Care Needs? Frederick Connell M.D., M.P.H. Child Health Institute, UW Medicaid Asthma Home Visit Project 	Completed Approved Conditionally Approved	A-092406-S B-070307-S A-082407-S
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 Exposure to Psychotropic Medications and Adverse Outcomes Dimitri Christakis M.D., M.P.H. UW / Child Health Institute The Year Following Myocardial Infarction: Patterns of Secondary Prevention in Washington James LoGerfo M.D., M.P.H. UW / Health Promotion Research Center Cost Effectiveness of Patient Review and Restriction Wei Yen Ph.D. DSHS Health & Recovery Services Administration Do Medical Homes Improve Health Care Quality for Children with Special Health Care Needs? Frederick Connell M.D., M.P.H. Child Health Institute, UW Medicaid Asthma Home Visit Project James Krieger, M.D., M.P.H. Public Health - Seattle & King County Mental Health Division Efficacy of a Bedtime Support Group for Middle School Inpatient Psychiatric Patients Gilda Warden M.A. DSHS / Child Study & Treatment Center Crisis Responder Pilot Evaluation Jim Mayfield M.A. Washington State Institute for Public Policy 	Completed Approved Conditionally Approved Pending Approved	A-092406-S B-070307-S A-082407-S D-122807-S B-092806-S

Validity of Risk Opinions in Juvenile Forensic Evaluations Frances Lexcen, Ph.D. DSHS / Child Study & Treatment Center	Exempt	B-041607-S
Religiosity, Religious Social Support, Post-Traumatic Growth, God Concept, and Recovery from Severe Mental Illness Kristin Hedden M.A. Seattle Pacific University / Dept of Clinical Psychology (graduate student)	Approved	B-050907-S
Partnership for Recovery: Transforming Mental Health in Washington Joseph Morrissey Ph.D. Center for Health Services Research / UNC at Chapel Hill	Cancelled	B-060407-S
Recovery and the Stigma of Mental Illness: A Study of Clinical Staff in Washington State's Public Health System Jennifer Stuber Ph.D. University of Washington / School of Social Work Special Commitment Center	Approved	B-101707-S
The Hare PSCAN and Its Relationship to Psychopathy in a		
Sample of Civilly Committed Sex Offenders Rebecca Jackson, Ph.D. Pacific Graduate School of Psychology	Exempt	B-110806-S
Changes in Modus Operandi and Victim Type in Recidivist Sex Offenders S. Wilcoxson Psy.D. DSHS / Special Commitment Center	Approved	A-123006-S
An Archival Study of the Rorschach Inkblot Test Administered on Sexually Violent Predators Bruce Duthie Ph.D. DSHS / Special Commitment Center	Pending	W-120707-S

DEPARTMENT OF HEALTH	Status	Study #
mmunity and Family Health		
Focus Group on Delayed Entry to HIV Medical Care: Barriers and Underlying Factors		
Maria Courogen M.P.H. DOH / Infectious Disease & Reproductive Health	Completed	A-080306
Epidemiology and Biostatistical Component of the Pratt & Whitney Cohort Mortality and Cancer Incidence Study Gary Marsh Ph.D. University of Pittsburgh	Cancelled	B-081806
The Effect of Maternal Mobility and Traffic Exposure on Adverse Reproductive Outcomes in Washington State Sylvia Brown M.P.H. University of Medicine and Dentistry of New Jersey	Approved	B-082406
Northwest Tribal Cancer Navigator Pilot Program Victoria Warren-Mears Ph.D. Northwest Portland Area Indian Health Board	Approved	A-092106
Impact of the Washington State Diabetes Collaborative on		
Patient Economic Outcomes Amira El-Bastawissi MBCHB, Ph.D. DOH / Community & Family Health	Approved	B-092206
Merkel Cell Carcinoma: What Makes a Difference? John Vetto M.D. Oregon Health & Sciences University	Approved	B-092306
Epidemiology and Biostatistical Component of the Pratt & Whitney Cohort Mortality & Cancer Incidence Study Gary Marsh Ph.D. University of Pittsburgh	Cancelled	B-120706
Evaluation of the Association Between Geographic Distribution and Clustering of Exemptions and Outbreak of Vaccine Preventable Diseases Saad Omer MBBS, M.P.H. Johns Hopkins School of Public Health	Cancelled	A-012207
Identifying Policies & Practices that Deter Access to Genetic Testing Services in Washington State Debra Lochner Doyle M.S., C.G.C. DOH / Genetics Services Section	Approved	A-020707
Surveillance of HIV-Related Events among Persons not		
Receiving HIV Care Maria Courogen M.P.H. DOH / Infectious Disease & Reproductive Health	Approved	A-051007
Early Hearing Loss Detection Diagnosis & Intervention Parent Survey Debra Lochner Doyle M.S., C.G.C. DOH / Maternal & Child Health	Approved	B-051507
Epidemiology and Biostatistical Component of the Pratt & Whitney Cohort Mortality & Cancer Incidence Study Gary Marsh Ph.D. University of Pittsburgh	Cancelled	B-060607
Predictors of Long-Term Outcome after a Diagnosis of Tuberculosis in Washington State	Cancelled	D-000007
Christopher Goss M.D., M.Sc. UW / Pulmonary/Critical Care Medicine	Approved	B-062107
NPAIHB Cancer Registry Linkage Victoria Warren-Mears Ph.D. Northwest Portland Area Indian Health Board	Approved	A-070307
Latino MSM HIV Prevention Needs Assessment Jason Carr M.P.H. DOH / Infectious Disease & Reproductive Health	Approved	A-080107
Cancer Epidemiology in Adventists, a Low Risk Group Gary Fraser M.D. Loma Linda University	Pending	B-103107

Olympic Medical Center Cancer Committee Annual Report Paul Stehr-Green, Dr.P.H. Olympic Medical Center Cancer Committee	Exempt	A-110907-H
Environmental Health Programs		
Identifying the Root Causes of Pesticide Illnesses Among Agricultural Workers James VanDerslice MSEE, Ph.D. DOH / Environmental Health	Approved	В-122106-Н
Epidemiology, Health Statistics, and Public Health Laboratories		
Predicting Risk of Childhood Lead Poisoning in Relatively High-Risk Counties in Washington Victor Van Hee M.D. UW / Occupational & Environmental Medicine	Cancelled	A-120506-H
Quality of Life, Overweight, and Smoking among Adolescents in Washington State		
Yan Guo UW / Department of Health Services	Exempt	A-121206-H
Effect of Length of Participation in WIC on Adverse Pregnancy Outcomes Amira El-Bastawissi MBCHB, Ph.D. DOH / Community & Family		
Health	Approved	B-122206-H
Role of Congenital Cytomegalovirus (CMV) Infection in Pediatric Hearing Loss Stephanie Misono M.D. UW / School of Medicine	Approved	B-122606-H
Is a Mandate for Physical Activity Policies Associated with Changes in School Programs & Student Behaviors? H. Mollie Greves M.D. UW / Child Health Institute	Approved	В-020507-Н
A Field Trial of Newborn Screening for Lysosomal Storage Diseases C. Ronald Scott M.D. UW / Department of Pediatrics	Cancelled	B-020607-H
Control Selection Methods for Childhood Cancer Studies Greta Bunin Ph.D. Children's Hospital of Philadelphia	Cancelled	A-022807-H
Predicting Risk of Childhood Lead Poisoning in Relatively High-Risk Counties in Washington Victor Van Hee M.D. UW / Occupational & Environmental Medicine	Approved	A-040907-H
Craniofacial Microsomia: The Vascular Disruption Hypothesis Jacqueline Starr Ph.D., M.P.H., M.S. Children's Hospital & Regional Medical Center	Approved	A-061507-H
Ambient Air Pollutant Exposure and Pre-Eclampsia, Pre- Term/Small Gestational Age Birth in the Puget Sound Air Basin		
Sheela Sathyanarayana M.D., M.P.H. UW / Department of Pediatrics	Approved	A-062207-H
Newborn Screening for Fabry Disease C. Ronald Scott M.D. UW / Department of Pediatrics	Approved	В-062707-Н
State-Specific Disparities in Maternal and Perinatal Morbidity Melissa Adams RN, MPH, PhD RTI International	Approved	B-083007-H
Healthy Youth Survey 2008 Lillian Bensley Ph.D. DOH / Non-Infectious Conditions Epidemiology	Conditionally Approved	A-091707-H
Enhancing the Size, Sampling, and Quality of Forensic mtDNA Databases Michael Coble, Ph.D. Armed Forces Institute of Pathology	Exempt	B-091807-H
	Litempt	11-10160-0
Early Combined Intervention after Traumatic Injury Douglas Zatzick, M.D. UW / Psychiatry and Behavioral Sciences	Pending	D-121707-H

'HELP' Depression and Suicide Prevention Curriculum		
Evaluation Marc Bolan Ph.D. Marc Bolan Consulting (Seattle, WA)	Approved	B-090806
Analysis of 2007 Registered Nurse Data from DOH Health		
Professions Licensing Survey		
Mark Doescher M.D., M.S.P.H. UW / Center for Health Workforce		
Studies	Approved	B-102907
Investigating the Outcomes of Motorcycle Collisions in the		
State of Washington		
Darwin N. Ang M.D., Ph.D. Harborview Medical Center	Deferred	A-110807
DEPARTMENT OF LABOR AND INDUSTRIES	Status	Study #
fety and Health Assessment and Research for Prevention HARP)		
Evaluating the Implementation & Impact of a Safe Patient Handling Law		
Barbara Silverstein Ph.D. Labor & Industries / SHARP	Approved	A-080206
surance Services		
Multistate Benchmark Reports by the Workers Compensation		
Research Institute		
Carol Telles J.D. Workers' Compensation Research Institute	Cancelled	A-110606
Occupational Injuries and Illness among Construction		
Workers in Washington State Sue Dong Dr.P.H. The Center to Protect Workers' Rights	Cancelled	A-111506
		111500
Linking Federal and State Data to Study the Economic Effects		
of Workplace Injury	Approved	A_07120 ⁻
Leslie Boden Ph.D. Boston University / School of Public Health	Approved	A-071307
Pensions System Review: Claims Abstracting and Analysis		
H. Allan Hunt, Ph.D. W.E. Upjohn Institute	Pending	D-122707
OTHER**	Status	Study #
	Jialus	Study #
Nurse-Mother Alliance Study		
Elizabeth Soliday Ph.D.	Cancelled	B-080106
Arts Impact/Arts Leadership		
Duane Baker Ed.D. The BERC Group	Cancelled	A-030807
Begin-at-Home Comparison Group		
Debra Srebnik Ph.D. King County - Mental Health and Chemical	Deferred	B-110707
	Deferred	B-110707
Debra Srebnik Ph.D. King County - Mental Health and Chemical Dependency Services Division Applying Health Information Technology to Improve	Deferred	B-110707
Debra Srebnik Ph.D. King County - Mental Health and Chemical Dependency Services Division	Deferred	B-110707 A-112107

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

	1945 Nuremberg Trials	
1940	 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 	
wwii	Nuremberg Code results – first legal attempt to deal with ethical issues of modern research	
	1953 NIH Requirement	
1950	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	History of Human Subjects Protection IN THE UNITED STATES
	 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	
1970	 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	
	1979 Belmont Report	
	The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research publishes recommendations, known as the Belmont	
1980	 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 rick or harm	
	 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 	
1990	1991 Title 45 CFR 46	
	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"	
	1996 and after Unified Standards	
2000	 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 	SOURCE (through 1991): University of Washington, Human
	1998 45 CFR Update	Subjects Division. Based on history compiled by the Fordham
	The federal Department of Health and Human Services adopts revised expedited review categories in 45 CFR Part 46	University Center for Ethics Education, NY. Information after 1991 provided by DSHS Human Research Review Section
2010	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 	

Protecting the Rights of Research Participants



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 websites: www.dshs.wa.gov/rda/hrrs

Promoting the Ethical Conduct of Research





