



**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**

WASHINGTON STATE Department of Social and Health Services Headquarters located at: 14th and Jefferson Street Olympia, WA 98504



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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

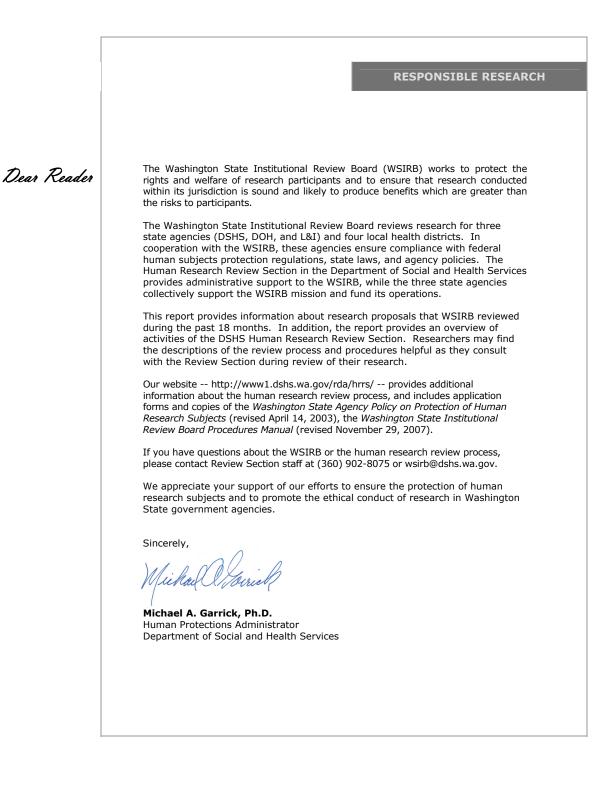
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## WASHINGTON STATE INSTITUTIONAL REVIEW BOARD A

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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**Sharon Durfy**, Ph.D. Research Scientist Illuminata, Inc.

Martha Holliday, M.P.H. Division Director Confederated Tribes of the Colville Reservation Vice Provost Department of Sociology Pacific Lutheran University **Maureen Marcenko,** M.S.W., Ph.D. Associate Professor

Associate Professor School of Social Work University of Washington

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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

| <b>Robert M. Fineman,</b> M.D., Ph.D.<br>Medical Consultant<br>DOH Newborn Screening Program                         | <b>Executive Secretary</b><br><b>Michael A. Garrick</b> , Ph.D.<br>Coordinator<br>DSHS Human Research Review<br>Section            |
|--|--|
| Members  | Associate Executive Secretary<br>Margaret Frederick, M.P.H., C.I.P.<br>Review Coordinator<br>DSHS Human Research Review<br>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  |
| <b>Kevin Campbell,</b> Dr.P.H.<br>Research Investigator<br>DSHS Division of Alcohol and<br>Substance Abuse           | Hanne Thiede, D.V.M., M.P.H.<br>Senior Epidemiologist<br>Public Health – Seattle and King<br>County                                |
| Substance Abuse  | county   |
| Maria Courogen, M.P.H.<br>Section Manager and Lead<br>Epidemiologist<br>DOH Infectious Disease &                     | <b>Dolf van den Heuvel,</b> Ph.D.<br>Lead Psychologist<br>DSHS Rainier School  |
| Reproductive Health  | Ronald Williams, M.D., M.P.H.<br>Medical Director  |
| <b>Barbara Burns McGrath,</b> Ph.D.<br>Research Associate Professor<br>School of Nursing<br>University of Washington | Yavapai County Detention Center  |
| <b>Lynne Clemmons Morris,</b><br>M.S.W., Ph.D.<br>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

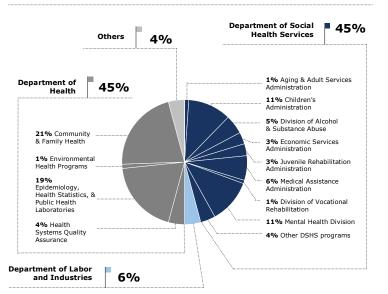
Washington Administrative Code: WAC 246-101 – Notifiable Conditions

## 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



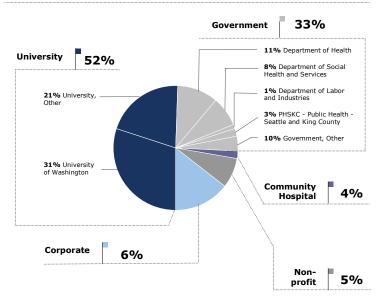
#### BY PROGRAM:

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<br>Patients with Refractory Epilepsy<br>Nicholas Poolos M.D., Ph.D.   Department of Neurology & Regional<br>Epilepsy Center / University of Washington<br>Children's Administration | Approved  | B-082707-S |
|   |           |            |
| Educational Attainment of Foster Youth: Updated<br>Achievement and Graduation Outcomes for Children in State<br>Care<br>Mason Burley M.P.A.   Washington State Institute for Public Policy  | Approved  | A-020807-S |
| Foster Care to College Partnership: Evaluating Postsecondary<br>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<br>Care Program   |           |            |
| Laura Schrager M.A.   Washington State Institute for Public Policy  | Approved  | A-031307-S |
| Infant Mental Health Dependency Court Project<br>Sheri Hill Ph.D.   UW / Center on Infant Mental Health &<br>Development  | Cancelled | B-032707-S |
|   | Cancelleu | D-032707-3 |
| King County Family Courts Study<br>Eric Trupin Ph.D.   UW / School of Medicine  | Approved  | B-050807-S |
| PETP Dependency Court Evaluations on the Psychosocial<br>Outcomes for Dependency Cases<br>Lisa Ferrari M.A.   Antioch University / graduate student   | Cancelled | B-053007-S |
| Skagit County Dependency Evaluation - Outcome Study<br>Andrew Benjamin Ph.D.   Antioch University Seattle & UW  | Approved  | B-080607-S |
| Foster Care Mental Health Consultation Pilot<br>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?<br>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<br>Eric Trupin Ph.D.   University of Washington  | Approved  | B-072606-S |
| Drug Treatment Completion & Retention Throughout  |           |            |
| Washington<br>Caleb Banta-Green M.P.H., M.S.W.   UW / School of Public Health<br>(doctoral student)   | Approved  | B-092506-S |
| King County Superior Court Reclaiming Futures Local   |           |            |
| <b>Evaluation</b><br>Peter Selby Ph.D.   TriWest Group  | Approved  | B-120606-S |

| RCT Evaluating Improvement Strategies in Addiction<br>Treatment<br>David Gustafson Ph.D.   University of Wisconsin / College of<br>Engineering<br>Division of Vocational Rehabilitation  | Approved  | B-051407-S   |
|--|---|--|
| WorkStrides<br>Elizabeth Swett Ph.D.   Western Washington University / Continuing<br>Education in Rehabilitation   | Approved  | A-072706-S   |
| Economic Services Administration   |   |  |
| Workforce Training Results: Vocational Rehabilitation and<br>WorkFirst Participants<br>Carl Wolfhagen, M.P.A.   Workforce Training & Education<br>Coordinating Board   | Exempt  | A-062707-S   |
| TANF Depression Study<br>Marna Miller Ph.D.   Washington State Institute for Public Policy   | Conditionally<br>Approved   | B-092007-S   |
| Juvenile Rehabilitation Administration   |   |  |
| Validation of the Self-Harm & Suicidal Behavior Screen for<br>JRA Youth: Pilot Work<br>André Ivanoff Ph.D.   Columbia University/School of Social Work   | Approved  | B-032907-S   |
| Students beyond Risk: Incarcerated Youth's Perspectives on Education<br>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<br>Dimitri Christakis M.D., M.P.H.   UW / Child Health Institute   | Cancelled   | A-071406-S   |
| Exposure to Psychotropic Medications and Adverse Outcomes  | Cancelled<br>Completed  | A-071406-S<br>A-092406-S   |
| Exposure to Psychotropic Medications and Adverse Outcomes<br>Dimitri Christakis M.D., M.P.H.   UW / Child Health Institute<br>The Year Following Myocardial Infarction: Patterns of<br>Secondary Prevention in Washington<br>James LoGerfo M.D., M.P.H.   UW / Health Promotion Research   |   |  |
| Exposure to Psychotropic Medications and Adverse Outcomes<br>Dimitri Christakis M.D., M.P.H.   UW / Child Health Institute<br>The Year Following Myocardial Infarction: Patterns of<br>Secondary Prevention in Washington<br>James LoGerfo M.D., M.P.H.   UW / Health Promotion Research<br>Center<br>Cost Effectiveness of Patient Review and Restriction   | Completed   | A-092406-S   |
| <ul> <li>Exposure to Psychotropic Medications and Adverse Outcomes<br/>Dimitri Christakis M.D., M.P.H.   UW / Child Health Institute</li> <li>The Year Following Myocardial Infarction: Patterns of<br/>Secondary Prevention in Washington<br/>James LoGerfo M.D., M.P.H.   UW / Health Promotion Research<br/>Center</li> <li>Cost Effectiveness of Patient Review and Restriction<br/>Wei Yen Ph.D.   DSHS Health &amp; Recovery Services Administration</li> <li>Do Medical Homes Improve Health Care Quality for Children<br/>with Special Health Care Needs?</li> </ul>   | Completed<br>Approved<br>Conditionally                                    | A-092406-S<br>B-070307-S   |
| <ul> <li>Exposure to Psychotropic Medications and Adverse Outcomes<br/>Dimitri Christakis M.D., M.P.H.   UW / Child Health Institute</li> <li>The Year Following Myocardial Infarction: Patterns of<br/>Secondary Prevention in Washington<br/>James LoGerfo M.D., M.P.H.   UW / Health Promotion Research<br/>Center</li> <li>Cost Effectiveness of Patient Review and Restriction<br/>Wei Yen Ph.D.   DSHS Health &amp; Recovery Services Administration</li> <li>Do Medical Homes Improve Health Care Quality for Children<br/>with Special Health Care Needs?<br/>Frederick Connell M.D., M.P.H.   Child Health Institute, UW</li> <li>Medicaid Asthma Home Visit Project</li> </ul>   | Completed<br>Approved<br>Conditionally<br>Approved                        | A-092406-S<br>B-070307-S<br>A-082407-S                             |
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| <ul> <li>Exposure to Psychotropic Medications and Adverse Outcomes     Dimitri Christakis M.D., M.P.H.   UW / Child Health Institute     </li> <li>The Year Following Myocardial Infarction: Patterns of         Secondary Prevention in Washington         James LoGerfo M.D., M.P.H.   UW / Health Promotion Research         Center     </li> <li>Cost Effectiveness of Patient Review and Restriction         Wei Yen Ph.D.   DSHS Health &amp; 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 &amp; King County         Mental Health Division         Efficacy of a Bedtime Support Group for Middle School         Inpatient Psychiatric Patients         Gilda Warden M.A.   DSHS / Child Study &amp; Treatment Center</li></ul>  | Completed<br>Approved<br>Conditionally<br>Approved                        | A-092406-S<br>B-070307-S<br>A-082407-S                             |
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| <ul> <li>Exposure to Psychotropic Medications and Adverse Outcomes<br/>Dimitri Christakis M.D., M.P.H.   UW / Child Health Institute</li> <li>The Year Following Myocardial Infarction: Patterns of<br/>Secondary Prevention in Washington<br/>James LoGerfo M.D., M.P.H.   UW / Health Promotion Research<br/>Center</li> <li>Cost Effectiveness of Patient Review and Restriction<br/>Wei Yen Ph.D.   DSHS Health &amp; Recovery Services Administration</li> <li>Do Medical Homes Improve Health Care Quality for Children<br/>with Special Health Care Needs?<br/>Frederick Connell M.D., M.P.H.   Child Health Institute, UW</li> <li>Medicaid Asthma Home Visit Project<br/>James Krieger, M.D., M.P.H.   Public Health - Seattle &amp; King County</li> <li>Mental Health Division</li> <li>Efficacy of a Bedtime Support Group for Middle School<br/>Inpatient Psychiatric Patients<br/>Gilda Warden M.A.   DSHS / Child Study &amp; Treatment Center</li> <li>Crisis Responder Pilot Evaluation<br/>Jim Mayfield M.A.   Washington State Institute for Public Policy</li> </ul>   | Completed<br>Approved<br>Conditionally<br>Approved<br>Pending<br>Approved | A-092406-S<br>B-070307-S<br>A-082407-S<br>D-122807-S<br>B-092806-S |

| Validity of Risk Opinions in Juvenile Forensic Evaluations<br>Frances Lexcen, Ph.D.   DSHS / Child Study & Treatment Center  | Exempt    | B-041607-S |
|--|-----------|------------|
| Religiosity, Religious Social Support, Post-Traumatic Growth,<br>God Concept, and Recovery from Severe Mental Illness<br>Kristin Hedden M.A.   Seattle Pacific University / Dept of Clinical<br>Psychology (graduate student)  | Approved  | B-050907-S |
| Partnership for Recovery: Transforming Mental Health in<br>Washington<br>Joseph Morrissey Ph.D.   Center for Health Services Research / UNC<br>at Chapel Hill  | Cancelled | B-060407-S |
| Recovery and the Stigma of Mental Illness: A Study of Clinical<br>Staff in Washington State's Public Health System<br>Jennifer Stuber Ph.D.   University of Washington / School of Social<br>Work<br>Special Commitment Center | Approved  | B-101707-S |
| The Hare PSCAN and Its Relationship to Psychopathy in a  |           |            |
| Sample of Civilly Committed Sex Offenders<br>Rebecca Jackson, Ph.D.   Pacific Graduate School of Psychology  | Exempt    | B-110806-S |
| Changes in Modus Operandi and Victim Type in Recidivist Sex<br>Offenders<br>S. Wilcoxson Psy.D.   DSHS / Special Commitment Center   | Approved  | A-123006-S |
| An Archival Study of the Rorschach Inkblot Test Administered<br>on Sexually Violent Predators<br>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<br>and Underlying Factors  |           |          |
| Maria Courogen M.P.H.   DOH / Infectious Disease & Reproductive Health  | Completed | A-080306 |
| Epidemiology and Biostatistical Component of the Pratt &<br>Whitney Cohort Mortality and Cancer Incidence Study<br>Gary Marsh Ph.D.   University of Pittsburgh  | Cancelled | B-081806 |
| The Effect of Maternal Mobility and Traffic Exposure on<br>Adverse Reproductive Outcomes in Washington State<br>Sylvia Brown M.P.H.   University of Medicine and Dentistry of New<br>Jersey                     | Approved  | B-082406 |
| Northwest Tribal Cancer Navigator Pilot Program<br>Victoria Warren-Mears Ph.D.   Northwest Portland Area Indian Health<br>Board   | Approved  | A-092106 |
| Impact of the Washington State Diabetes Collaborative on  |           |          |
| Patient Economic Outcomes<br>Amira El-Bastawissi MBCHB, Ph.D.   DOH / Community & Family<br>Health  | Approved  | B-092206 |
| Merkel Cell Carcinoma: What Makes a Difference?<br>John Vetto M.D.   Oregon Health & Sciences University  | Approved  | B-092306 |
| Epidemiology and Biostatistical Component of the Pratt &<br>Whitney Cohort Mortality & Cancer Incidence Study<br>Gary Marsh Ph.D.   University of Pittsburgh  | Cancelled | B-120706 |
| Evaluation of the Association Between Geographic Distribution<br>and Clustering of Exemptions and Outbreak of Vaccine<br>Preventable Diseases<br>Saad Omer MBBS, M.P.H.   Johns Hopkins School of Public Health | Cancelled | A-012207 |
| Identifying Policies & Practices that Deter Access to Genetic<br>Testing Services in Washington State<br>Debra Lochner Doyle M.S., C.G.C.   DOH / Genetics Services Section                                     | Approved  | A-020707 |
| Surveillance of HIV-Related Events among Persons not  |           |          |
| <b>Receiving HIV Care</b><br>Maria Courogen M.P.H.   DOH / Infectious Disease & Reproductive<br>Health  | Approved  | A-051007 |
| <b>Early Hearing Loss Detection Diagnosis &amp; Intervention Parent</b><br><b>Survey</b><br>Debra Lochner Doyle M.S., C.G.C.   DOH / Maternal & Child Health  | Approved  | B-051507 |
| Epidemiology and Biostatistical Component of the Pratt &<br>Whitney Cohort Mortality & Cancer Incidence Study<br>Gary Marsh Ph.D.   University of Pittsburgh  | Cancelled | B-060607 |
| Predictors of Long-Term Outcome after a Diagnosis of<br>Tuberculosis in Washington State  | Cancelled | D-000007 |
| Christopher Goss M.D., M.Sc.   UW / Pulmonary/Critical Care<br>Medicine   | Approved  | B-062107 |
| NPAIHB Cancer Registry Linkage<br>Victoria Warren-Mears Ph.D.   Northwest Portland Area Indian Health<br>Board  | Approved  | A-070307 |
| Latino MSM HIV Prevention Needs Assessment<br>Jason Carr M.P.H.   DOH / Infectious Disease & Reproductive Health  | Approved  | A-080107 |
| Cancer Epidemiology in Adventists, a Low Risk Group<br>Gary Fraser M.D.   Loma Linda University   | Pending   | B-103107 |

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

| 'HELP' Depression and Suicide Prevention Curriculum   |           |                      |
|---|-----------|----------------------|
| <b>Evaluation</b><br>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<br>HARP)   |           |                      |
|   |           |                      |
| Evaluating the Implementation & Impact of a Safe Patient<br>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<br>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 <sup>-</sup> |
| 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<br>Dependency Services Division<br>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<br>A-112107 |

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

|      | 1945<br>Nuremberg Trials   |   |
|------|--|---|
| 1940 | <ul> <li>Medical experimentation abuses by Nazi doctors comes to public attention</li> <li>United States, Great Britain, France and Russia charge 24 men and six organizations with systematic murder of millions of people</li> </ul>   |   |
| wwii | Nuremberg Code results – first legal attempt to deal with ethical issues of modern research  |   |
|      | 1953<br>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<br>Subjects Protection<br>IN THE UNITED STATES   |
|      | <ul> <li>1964</li> <li>Declaration of Helsinki</li> </ul>  |   |
|      | 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<br>First Regulations  |   |
|      | <ul> <li>United States Public Health Service issues its first set of regulations extending a review requirement to all "extramural" research supported by the agency</li> <li>Revisions in 1971 and 1974 lead to Institutional Review Boards (IRBs) at hundreds of institutions receiving federal funding for research</li> </ul>          |   |
|      | 1972<br>Tuskegee Study   |   |
| 1970 | <ul> <li>Public disclosure prompts the cancellation of 40-year government-supported<br/>Tuskegee Syphilis Study in which 300 black rural men were left untreated for<br/>diagnosed syphilis, even after effective antibiotics became available</li> <li>Public Law 93-348 results, establishing the National Commission for the</li> </ul> |   |
|      | Protection of Human Subjects of Biomedical and Behavioral Research   |   |
|      | 1979<br>Belmont Report   |   |
|      | The National Commission for the Protection of Human Subjects of Biomedical<br>and Behavioral Research publishes recommendations, known as the Belmont  |   |
| 1980 | <ul> <li>Report, that serve as the basis for revised federal regulations published in the Federal Register in 1979</li> <li>Three general ethical principles provide a framework for human subjects</li> </ul>   |   |
|      | research:<br><b>1. Beneficence:</b> To maximize benefits for science, humanity, and research<br>participants and to avoid or minimize rick or harm   |   |
|      | <ul> <li>participants and to avoid or minimize risk or harm</li> <li><b>2. Respect:</b> To protect the autonomy and privacy rights of participants</li> <li><b>3. Justice:</b> To ensure the fair distribution among persons and groups of the costs and benefits of research</li> </ul>   |   |
| 1990 | 1991<br>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<br>Unified Standards  |   |
| 2000 | <ul> <li>International Conference on Harmonization, Good Clinical Practice</li> <li>Guidelines unifies standards for European Union, Japan, and United States to facilitate mutual acceptance of clinical trial data by respective regulatory authorities</li> </ul>   | SOURCE (through 1991):<br>University of Washington, Human   |
|      | 1998<br>45 CFR Update  | Subjects Division. Based on<br>history compiled by the Fordham  |
|      | The federal Department of Health and Human Services adopts revised<br>expedited review categories in 45 CFR Part 46  | University Center for Ethics<br>Education, NY.<br>Information after 1991 provided<br>by DSHS Human Research<br>Review Section |
| 2010 | 2001<br>Pregnant women   |   |
|      | <ul> <li>The federal Department of Health and Human Services issues revised<br/>Subpart B, Additional Protections for Pregnant Women, Human Fetuses<br/>and Neonates permitting research with pregnant women, in most cases<br/>leaving decision-making to the woman</li> </ul>  |   |

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





