ACTIVITY REPORT

Washington State
Institutional Review Board

January – December 2008

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

April 2009
Information About this Publication


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 2008. 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 2008

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Author: Michael A. Garrick, Ph.D.

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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 (DHS, 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 2008. 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.


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

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

Sincerely,

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

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WASHINGTON STATE INSTITUTIONAL REVIEW BOARD

Chair
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Senior Epidemiologist
Public Health – Seattle and King County

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Coordinator
DSHS Human Research Review Section

Associate Executive Secretary
Margaret Frederick, M.P.H., C.I.P.
Review Coordinator
DSHS Human Research Review Section

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Prisoner Representative

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DSHS Aging & Disability Services Administration

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Pharmacist
DSHS Western State Hospital

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Associate Medical Director – SHARP
Department of Labor & Industries

Cindy Bouillon-Jensen, M.A., C.I.P.
Consultant
Human Subjects Protections

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Research Investigator
DSHS Division of Alcohol and Substance Abuse

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Division Director
Confederated Tribes of the Colville Reservation

Anna Y. Leon-Guerrero, Ph.D.²
Vice Provost and Chair
Department of Sociology
Pacific Lutheran University

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School of Social Work
University of Washington

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Research Associate Professor
School of Nursing
University of Washington

Lynne Clemmons Morris, M.S.W., Ph.D.²
Associate Professor, Social Work
Eastern Washington University

Robert D. Mootz, D.C.²
Associate Medical Director for Chiropractic
Department of Labor & Industries

Melanie Payne, M.P.H.³
Epidemiologist
Clark County Health Department

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Executive Director
Marsha Rivkin Center for Ovarian Cancer Research

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

Robert M. Fineman, M.D., Ph.D.
Dean, Health & Human Services Div.
North Seattle Community College

Ronald Williams, M.D., M.P.H.¹
Medical Director
Arizona Department of Juvenile Corrections

¹ Ad Hoc member
² Rotating member

Antonio Garcia, M.S.W.
Student
School of Social Work
University of Washington
REVIEW BOARD ORGANIZATION AND MEMBERSHIP

Composition of the Review Board

The Washington State Institutional Review Board consists of members with varying backgrounds to promote complete and adequate review of research activities conducted within the jurisdiction of the three Washington State Agencies: DSHS, DOH, and L&I.

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

Appointment of Board members

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

Length of Service

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

Duties

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

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

Conflict of Interest

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

Confidentiality of Materials

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

2008

Consolidated Review Board
The WSIRB held its first meeting as a combined committee on January 17, 2008. The consolidated committee is comprised of members from the former Review Board A and Review Board B, and now includes individuals who serve as rotating alternates for other WSIRB members. This change should ensure that quorum requirements are easily met and will provide greater flexibility in assigning proposals to a Primary Reviewer. Consolidation also entails more frequent meetings, with 12 scheduled meetings per year, two of which are telephone conferences. The monthly schedule will assist researchers in timely review of their proposals. Previously, WSIRB meetings were held 6-7 weeks apart.

The Review Board had consisted of two committees since 1990. Efficiencies in the review process lead to the decision to merge the two Boards into one.

New Board Chair
Hanne Thiede, DVM, MPH, became Chair of the WSIRB in January 2008. Dr. Thiede is a Senior Epidemiologist for Public Health-Seattle and King County. Review Board procedures were changed to permit individuals who are not employees of the three state agencies to serve as Chair. Dr. Thiede has been a Review Board member since January 1999.

WSIRB Membership
With consolidation, the WSIRB welcomed two new members. Antonio Garcia, MSW, is working toward his dissertation in child welfare at the University of Washington. He has extensive experience in child welfare, having worked as a social worker with the DSHS Division of Children and Family Services for a number of years.

Cindy Barchiesi, PharmD, has been a clinical pharmacist at Western State Hospital for over 20 years. She currently works as a Clinical Forensic Pharmacist at the hospital. After attending WSIRB meetings for one year, Dr. Barchiesi will become an ad hoc member in 2009, specializing in research in the two state hospitals and pharmaceutical research.

Dennis McBride, PhD, Washington Institute for Mental Health Research and Training, completed his term of service in June 2008. Dr. McBride had served on the WSIRB for 16 years, five of them as Board Chair.

Samantha Asbjornsen, MSW, LICSW, resigned from the Review Board in December 2008. Ms. Asbjornsen, who served on the Review Board for two years, provided valuable social work expertise to Board deliberations.

Quality Improvement Activities
Training: The WSIRB began regular in-service training for Review Board members at convened meetings. The first in-service was conducted in January 2008. In-service training is designed to ensure that Board members remain current with regulatory issues and other aspects of human subject protections, focusing on the "how-to" of review.

The 9 training sessions conducted during 2008 focused on the duties and responsibilities of WSIRB members; the Belmont Report; the risks and benefits of social and behavioral research; confidentiality agreements; how to review a proposal; improving the consent process; research with prisoners; waivers of authorization; and use and disclosure of identifiable records for research.

All in-service training materials are posted on the WSIRB website. Several checklists to assist WSIRB members in review of proposals have also been developed.

Customer Survey: The Review Section conducted a customer service survey of Juvenile Rehabilitation Administration program managers and administrators in April. Survey participants were asked about their awareness of the WSIRB and the Human Research Review Section, their opinions of the WSIRB website, and how they have handled inquiries regarding research in JRA in the past. Survey results were provided to all individuals in the sample frame.

Review Process: Consolidation of the Review Board and more frequent meetings lead to a change in the pre-review process for proposals that require full committee review. Pre-reviews are now conducted by IRB staff; Primary Reviewers are no longer involved in this process. The change was necessary due to the shorter timeframe between WSIRB meetings.

Certification as an IRB Professional:
In October, Maggie Frederick passed the recertification exam for IRB professionals. Ms. Frederick was the first WSIRB member to be certified, in October 2005. WSIRB member Cindy Bouillon-Jensen achieved certification in 2007. The exam and certification process is designed to promote ethical research practices and programs by ensuring that IRB members and administrators have demonstrated an advanced level of applied knowledge of human subject protections. Individuals who obtain the designation of Certified IRB Professional (CIP) must be recertified every 3 years.

Contacts with Local IRB:
Several groups of Fellows participating in a Western IRB/World Health Organization program to improve human subject protections in other countries attended WSIRB meetings during 2008. Western IRB attendees included Ted Schultz, J.D., Kay King, J.D., Mitchell Parrish, J.D., and Bradley E Waite, D.O. Nineteen Fellows, comprising health care professionals, IRB members, or IRB Chairs, hailed from Korea, Cameroon, Taiwan, China, Peru, Taipei, and Russia.
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 subjects protection 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
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 2008

The following research applications were submitted for WSIRB review from January through December 2008. They are categorized by the program area in which the research will occur or the source of research subjects (see page 6 of this Report for an explanation). The “status” code indicates each application’s status at the end of 2008. 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

Aging and Adult Services

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<tr>
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<tr>
<td>Assessing the Costs and Benefits of Public Guardianship Services</td>
<td>Deferred</td>
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<tr>
<td>Mason Burley M.P.A.</td>
<td>Washington State Institute for Public Policy</td>
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Children’s Administration

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<tr>
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<tr>
<td>Project Focus</td>
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<tr>
<td>Eric Trupin, Ph.D.</td>
<td>University of Washington / School of Medicine</td>
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<tr>
<th>Study</th>
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<tr>
<td>Transitions to Adulthood: Outcome Analysis Using Administrative Data</td>
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<tr>
<td>Laura Schrager, M.A.</td>
<td>Washington State Institute for Public Policy</td>
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<tr>
<td>ACY-ACYF Grant (RPSC Program)</td>
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<tr>
<td>Geoffrey Miller, M.B.A.</td>
<td>Geo Education and Research</td>
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<tr>
<th>Study</th>
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<tr>
<td>Fostering Adolescents: A Foster Parent Perspective on Raising Adolescents in Foster Care</td>
<td>Approved</td>
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<td>William Bell, M.S.W.</td>
<td>Casey Family Programs</td>
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<th>Study</th>
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<tr>
<td>Children’s Administration Practice Model Evaluation—Parent Interviews</td>
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<td>Mark Courtney, Ph.D.</td>
<td>University of Washington / Partners for Our Children</td>
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<th>Study</th>
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<tr>
<td>Foster Parent Support Pilot Study</td>
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<tr>
<td>Maureen Marcenko, Ph.D.</td>
<td>University of Washington / School of Social Work</td>
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<th>Study</th>
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<tr>
<td>Looking at Follow-Up of CHET Screening Reports</td>
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<tr>
<td>Kimmy Van</td>
<td>University of Washington (graduate student)</td>
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<td>Fostering Hope Project</td>
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<td>Shannon Dorsey, Ph.D.</td>
<td>University of Washington / School of Medicine</td>
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<th>Study</th>
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<tr>
<td>Foster Care to College Partnership, Evaluating Postsecondary Outcomes for Foster Youth</td>
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<td>Laura Schrager, M.A.</td>
<td>Washington State Institute for Public Policy</td>
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<tr>
<td>A Study of Placement Stability in Washington State</td>
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<tr>
<td>Fred Wulczyn, Ph.D.</td>
<td>Chapin Hall Center, University of Chicago</td>
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<td>Fathers Engagement Project</td>
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<td>Carol Harper, M.P.A</td>
<td>University of Washington / School of Social Work</td>
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<tr>
<td>Foster Care to College Partnership: Evaluating Postsecondary Outcomes for Foster Youth</td>
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<td>Laura Schrager, M.A.</td>
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<tr>
<td>Multi-System Prevalence Study</td>
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<tr>
<td>Gregg Halemba, M.A.</td>
<td>National Center for Juvenile Justice</td>
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</table>
### Division of Alcohol and Substance Abuse

**Gender-Sensitive Treatment in Mixed Gender Programs - The Quantitative Component**  
Robert Orwin Ph.D. | WESTAT  
Approved D-012408-S

**Client Outcomes for Oregon and Washington NIATx Participants**  
Kim Hoffman Ph.D. | Oregon Health & Science University  
Approved D-042808-S

**Gender-Sensitive Treatment in Mixed Gender Programs - The Qualitative Component (Site Visit)**  
Robert Orwin Ph.D. | WESTAT  
Approved D-042908-S

**Evaluation of the PROMETA Protocol**  
Dennis Donovan Ph.D. | Alcohol & Drug Abuse Institute  
Cancelled D-060108-S

**Effect of Intimate Partner Violence and Co-Occurring Disorders on Substance Abuse Treatment Outcomes**  
Sherry Lipsky Ph.D. | Harborview Medical Center  
Approved D-062008-S

**Intensive Case Management Pilot Program Evaluation**  
Melissa Ford Shah  M.P.P. | DSHS Research & Data Analysis  
Approved D-082708-S

**Evaluation of the Clark County Sales Tax Revenue for Chemical Dependency, Mental Health, and Therapeutic Courts**  
Clayton Mosher Ph.D. | Washington State University-Vancouver / Department of Sociology  
Approved D-100808-S

### Division of Developmental Disabilities

**Norming the Children’s Version of the Support Intensity Scale in WA State**  
Lisa Weber Ph.D. | DSHS Division of Developmental Disabilities  
Approved D-042408-S

**The Experience of Change for Adults with Developmental Disabilities**  
Mary Ann Clute, Ph.D. | Eastern Washington University  
Approved D-072208-S

**Children’s Intensive In-Home Behavioral Support Program Evaluation**  
Lisa Weber Ph.D. | DSHS Division of Developmental Disabilities  
Cancelled D-083108-S

### Juvenile Rehabilitation Administration

**National Survey of Youth in Custody (NSYC)**  
David Cantor Ph.D. | WESTAT  
Approved D-052908-S

**JRA Acuity Screen Development**  
Sarah Susworth Walker Ph.D. | University of Washington / Public Behavioral Health & Justice Policy  
Approved D-090808-S

**Research Participation among Incarcerated Adolescents**  
André Ivanoff Ph.D. | DSHS Juvenile Rehabilitation Administration  
Conditionally Approved D-122608-S
### Medical Assistance

<table>
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<tr>
<th>Study Title</th>
<th>Principal Investigator</th>
<th>Institution(s)</th>
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<tr>
<td><strong>Do Medical Homes Improve Health Care Quality for Children with</strong></td>
<td>Frederick Connell M.D., M.P.H.</td>
<td>University of Washington / Child Health Institute</td>
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<td>D-011608-S</td>
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<td><strong>with Special Health Care Needs?</strong></td>
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<td><strong>Primary Care Psychiatry Consultation and Training for Youth Receiving</strong></td>
<td>Eric Trupin Ph.D.</td>
<td>University of Washington / School of Medicine</td>
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<td><strong>Medicaid (PAL)</strong></td>
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<td><strong>Long-Term Cost Outcome of Pediatric Burn Injury</strong></td>
<td>Matthew Klein M.D.</td>
<td>Harborview Medical Center</td>
<td>Approved</td>
<td>D-033108-S</td>
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<td><strong>Exposure to Medications and Adverse Cardiac Outcomes</strong></td>
<td>Frederick Connell M.D., M.P.H.</td>
<td>University of Washington / Child Health Institute</td>
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<td><strong>A Multi-State Study of Cancer Treatment and Outcomes Among American</strong></td>
<td>Scott Ramsey M.D., Ph.D.</td>
<td>Fred Hutchinson Cancer Research Center</td>
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<td><strong>Indians</strong></td>
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<td><strong>A Claims-Based Algorithm to Identify Incident Cases of Non-Small Cell</strong></td>
<td>Scott Ramsey M.D., Ph.D.</td>
<td>Fred Hutchinson Cancer Research Center</td>
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<td><strong>Lung Cancer</strong></td>
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### Mental Health Division

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<tr>
<td><strong>Journey to Life Wellness Program Evaluation</strong></td>
<td>Dennis McBride, Ph.D.</td>
<td>Washington Institute for Mental Health Research &amp; Training</td>
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<td><strong>QA/QI Evaluation of CFS Screening Form</strong></td>
<td>Aaron Hunt, M.D.</td>
<td>DSHS / Western State Hospital</td>
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<td><strong>FACT Program Evaluation</strong></td>
<td>Genevieve Rowe, M.S.</td>
<td>King County / Mental Health Chemical Abuse &amp; Dependency Services</td>
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<td><strong>Evaluation of Washington State Wraparound Pilot Project</strong></td>
<td>Eric Bruns, Ph.D.</td>
<td>University of Washington / School of Medicine</td>
<td>Approved</td>
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<td><strong>Evaluation of Seattle School-Based Health Centers</strong></td>
<td>Eric Bruns, Ph.D.</td>
<td>University of Washington / School of Medicine</td>
<td>Conditionally Approved</td>
<td>D-082808-S</td>
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<td><strong>Evaluation of the Treatment Mall at Eastern State Hospital</strong></td>
<td>Aja Matthews, B.A.</td>
<td>Eastern Washington University / School of Social Work (graduate student)</td>
<td>Conditionally Approved</td>
<td>D-082908-S</td>
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<td><strong>Children’s Mental Health Evidence-Based Practice Pilot</strong></td>
<td>Jim Mayfield, M.A.</td>
<td>Washington State Institute for Public Policy</td>
<td>Conditionally Approved</td>
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### Special Commitment Center

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<td><strong>Washington State Sex Offender Risk Assessment Initiative</strong></td>
<td>Rebecca Jackson, Ph.D.</td>
<td>Pacific Graduate School of Psychology</td>
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<td><strong>Mentally Ill Offenders: A Comparison of Commitment Standards</strong></td>
<td>Rebecca Jackson, Ph.D.</td>
<td>Pacific Graduate School of Psychology</td>
<td>Approved</td>
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### Community and Family Health

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<tr>
<td>WSC Impact on Economic Outcomes of Diabetes Patients on Medicaid</td>
<td>Amira El-Bastawissi, MBCHB, Ph.D.</td>
<td>DOH / Community and Family Health</td>
<td>Approved</td>
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<tr>
<td>Adventist Health Study - 2</td>
<td>Gary Fraser, M.D., Ph.D.</td>
<td>Loma Linda University</td>
<td>Approved</td>
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<td>Blinded HIV Seroprevalence Survey of Incoming Inmates in a Washington State Correctional Facility</td>
<td>Maria Courogen, M.P.H.</td>
<td>DOH / Infectious Disease/Reproductive Health</td>
<td>Approved</td>
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<td>Cancer Incidence and Cancer Morality in the World Trade Center Health Registry</td>
<td>Mark Farfel, Sc.D.</td>
<td>New York City Dept of Health and Mental Hygiene</td>
<td>Approved</td>
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<td>Youth Health Risk Survey</td>
<td>Stacy Wenzl, M.P.H.A.</td>
<td>Spokane Regional Health District</td>
<td>Approved</td>
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<tr>
<td>Epidemiology and Biostatistical Component of the Pratt &amp; Whitney Cohort Mortality &amp; Cancer Incidence Study</td>
<td>Gary Marsh Ph.D.</td>
<td>University of Pittsburgh</td>
<td>Conditionally Approved</td>
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### Epidemiology, Health Statistics, and Public Health Laboratories

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Researcher(s)</th>
<th>Status</th>
<th>Study #</th>
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<tbody>
<tr>
<td>Surgical Clinical Outcomes Assessment Programs</td>
<td>David Flum, M.D.</td>
<td>University of Washington Medical Center</td>
<td>Approved</td>
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<tr>
<td>Association of Surgical Volume with Reoperation Rates Following Lumbar Spine Surgery in Washington State</td>
<td>Brook Martin, M.P.H.</td>
<td>University of Washington / School of Public Health (doctoral student)</td>
<td>Approved</td>
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<tr>
<td>Diabetes Evaluation in Washington (DEW-IT) 2</td>
<td>William Hagopian, M.D., Ph.D.</td>
<td>Pacific Northwest Diabetes Research Institute</td>
<td>Approved</td>
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<tr>
<td>Hematopoietic Cell Transplantation - Hospital Discharge Data Linkage Study</td>
<td>Eric Chow, M.D.</td>
<td>Fred Hutchinson Cancer Research Center</td>
<td>Approved</td>
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<tr>
<td>Pre-Hospital Care of the Patient with Non-Traumatic Hypotension in King County</td>
<td>Thomas Rea, M.D., M.P.H.</td>
<td>University of Washington / School of Medicine</td>
<td>Approved</td>
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<tr>
<td>Long-Term Outcomes of Pediatric Out-of-Hospital Cardiac Arrest</td>
<td>Erica Michiels, M.D.</td>
<td>University of Washington / School of Medicine</td>
<td>Conditionally Approved</td>
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<tr>
<td>Variation in Surgical Care for Gastrointestinal Cancers</td>
<td>David Flum, M.D.</td>
<td>University of Washington Medical Center</td>
<td>Approved</td>
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<tr>
<td>Evaluation of Agricultural Related Environmental Factors Associated with Increased Risk of Gastroschisis in Washington State</td>
<td>Sarah Waller, M.D.</td>
<td>University of Washington / School of Medicine</td>
<td>Approved</td>
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<td>Study title</td>
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<td><strong>Campylobacteriosis Risk Factors in Dairy Counties</strong></td>
<td>Margaret Davis, D.V.M., M.P.H., Ph.D.</td>
<td>Washington State University / Veterinary Microbiology</td>
<td>Conditionally Approved</td>
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<tr>
<td><strong>A Population-Based Analysis of Care and Outcomes for Cholecystectomy in the State of Washington</strong></td>
<td>David Flum, M.D.</td>
<td>University of Washington/ Medical Center</td>
<td>Deferred</td>
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<tr>
<td><strong>Collective Efficacy, Migration Patterns, Crime, and Health Outcomes in Seattle Neighborhoods</strong></td>
<td>Ross Matsueda, Ph.D.</td>
<td>University of Washington / Department of Sociology</td>
<td>Conditionally Approved</td>
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**Health Systems Quality Assurance**

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<td><strong>Look, Listen, and Link Curriculum Evaluation</strong></td>
<td>Marc Bolan Ph.D.</td>
<td>Approved</td>
<td>D-060308-H</td>
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**DEPARTMENT OF LABOR AND INDUSTRIES**

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<td><strong>Safety and Health Assessment and Research for Prevention (SHARP)</strong></td>
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<td><strong>Workplace Violence in Washington State Psychiatric Hospitals</strong></td>
<td>Barbara Silverstein Ph.D.</td>
<td>Labor &amp; Industries / SHARP</td>
<td>Cancelled</td>
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<tr>
<td><strong>An Evaluation of Ergonomic Process Changes in an Aluminum Rolling Plant</strong></td>
<td>Stephen Bao, Ph.D.</td>
<td>Labor &amp; Industries / SHARP</td>
<td>Conditionally Approved</td>
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<tr>
<td><strong>Ergonomic Evaluation of Bill Processing Jobs</strong></td>
<td>Barbara Silverstein Ph.D.</td>
<td>Labor &amp; Industries / SHARP</td>
<td>Conditionally Approved</td>
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**OTHER**

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<td><strong>Evaluation of Remote Infrared Audible Signage</strong></td>
<td>Margaret Petrella, M.A.</td>
<td>US Department of Transportation</td>
<td>Cancelled</td>
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<tr>
<td><strong>Evaluation of Remote Infrared Audible Signage</strong></td>
<td>Margaret Petrella, M.A.</td>
<td>US Department of Transportation</td>
<td>Approved</td>
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<tr>
<td><strong>Sound Transit Evaluation of Remote Infrared Audible Signage (RIAS)</strong></td>
<td>Michael Miller, B.A.</td>
<td>Central Puget Sound Regional Transit Authority</td>
<td>Conditionally Approved</td>
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**Reviewed at the request of the researcher's home institution; not otherwise in WSIRB jurisdiction.**
In 2004, the Review Section formalized a procedure for requesting exemption from human subjects review. Agency staff and other researchers whose activities may be under the jurisdiction of the WSIRB are asked to submit an Exempt Determination Request by email to the WSIRB. The form is available at http://www.dshs.wa.gov/rda/hrrs/default.shtm.

Requests for exemption have a short turn-around time, usually within one week of receipt. The Request form incorporates a three-stage approach to determine:

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

A summary of the activity must accompany the Request form. Individuals who submit a Request receive a written determination of whether the activity requires WSIRB review. Most activities are determined to not be research (e.g., quality improvement/quality assurance, needs assessment, marketing, etc.) About 10% of Requests are determined to be research that is not exempt.

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

The exempt process provides an easy, efficient way for agency staff and researchers to check if an activity requires WSIRB review. In addition, peer-reviewed journals frequently ask for documentation of IRB review before they will consider accepting an article for publication. Documentation that an activity was exempt from human subjects review can assist with meeting publication requirements.
1940

World War II

1945

Nuremberg Trials

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

1950

NIH Requirement

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

1964

Declaration of Helsinki

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

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

1970

Tuskegee Study

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

1979

Belmont Report and Title 45 CFR 46

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

1991

Common Rule

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

1996

Unified Standards

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

1998

45 CFR Update

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

2000

Pregnant women

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

2003

Health Insurance Portability and Accountability Act (HIPAA)

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

Promoting the Ethical Conduct of Research

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