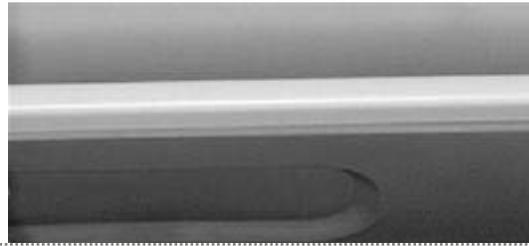


ACTIVITY REPORT

April 2009

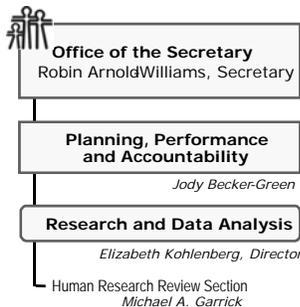
**Washington State
Institutional Review Board
January – December 2008**



**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



HRRS/WSIRB

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Information About this Publication

Title: Washington State Institutional Review Board, January – December 2008

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 (DSHS, DOH, and L&I) and four local health districts. In cooperation with the WSIRB, these agencies ensure compliance with federal human subject protections regulations, state laws, and agency policies. The Human Research Review Section in the Department of Social and Health Services provides administrative support to the WSIRB, while the three state agencies collectively support the WSIRB mission and fund its operations.

This report provides information about research proposals that WSIRB reviewed during 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.

Our website -- <http://www.dshs.wa.gov/rda/hrrs/> -- provides additional information about the human research review process, and includes application forms and copies of the *Washington State Agency Policy on Protection of Human Research Subjects* (revised April 14, 2003), the *Washington State Institutional Review Board Procedures Manual* (revised December 18, 2008).

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

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

Sincerely,



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

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WASHINGTON STATE INSTITUTIONAL REVIEW BOARD

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Public Health – Seattle and King
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Section

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Prisoner Representative

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Social Worker
DSHS Aging & Disability Services
Administration

Cindy Barchiesi, Pharm.D.¹
Pharmacist
DSHS Western State Hospital

David Bonauto, M.D., M.P.H.
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Department of Labor & Industries

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

Kevin Campbell, Dr.P.H.
Research Investigator
DSHS Division of Alcohol and
Substance Abuse

Maria Courogen, M.P.H.
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Epidemiologist
DOH Infectious Disease &
Reproductive Health

M. Patricia deHart, Sc.D.
Epidemiologist
DOH Immunization Project

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

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Dean, Health & Human Services Div.
North Seattle Community College

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Associate Professor
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DOH Center for Health Statistics

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

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

¹ Ad Hoc member

² Rotating member

REVIEW BOARD ORGANIZATION AND MEMBERSHIP

Composition of the Review Board

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

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

Appointment of Board members

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

Length of Service

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

Duties

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

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

Conflict of Interest

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

Confidentiality of Materials

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



For more information see: Washington State Institutional Review Board Procedures Manual at <http://www.dshs.wa.gov/pdf/ms/rda/hrrs/Procedures.pdf>

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.

LEGAL AUTHORITY



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

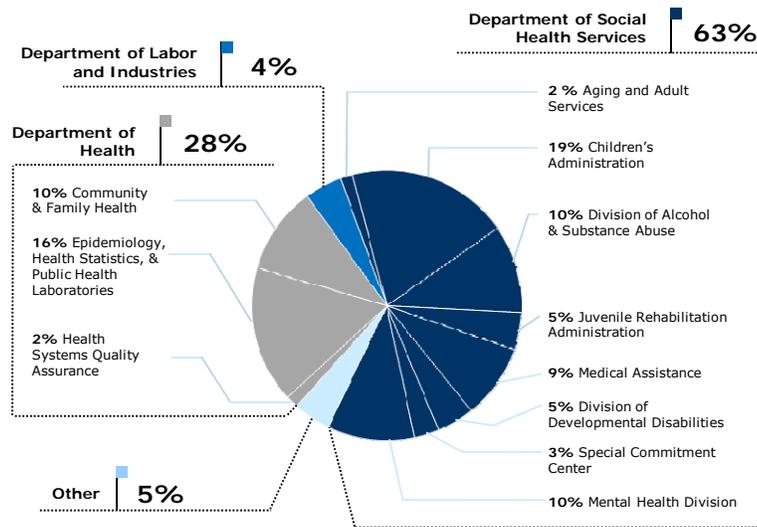
STATE AGENCY POLICIES

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

STATISTICS

AGENCY PROGRAM

January- December 2008 | Proposals reviewed: 67



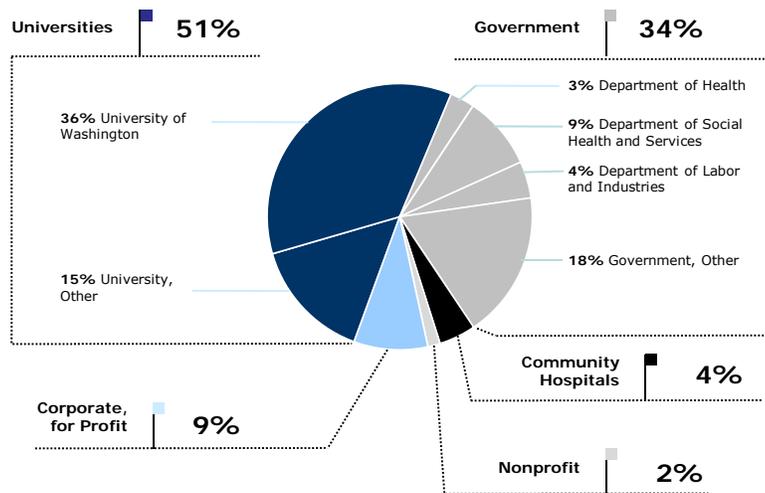
AGENCY PROGRAM:

The Department of Social and Health Services and Department of Health together accounted for 91% and Department of Labor and Industries had 5% of all the new proposals reviewed during 2008.

Source: WSIRB Dec 31, 2008

RESEARCHER AFFILIATION

January – December 2008 | Proposals Reviewed: 67



RESEARCHER AFFILIATION:

Fifty-one percent of the principal investigators were university-based, with the University of Washington accounting for the large majority. The other 49% of researchers were affiliated with Government, Corporate, Community Hospitals, and Nonprofit.

Source: WSIRB Dec 31, 2008

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	Status	Study #
Aging and Adult Services		
Assessing the Costs and Benefits of Public Guardianship Services Mason Burley M.P.A. Washington State Institute for Public Policy	Deferred	D-110708-S
Children's Administration		
Project Focus Eric Trupin, Ph.D. University of Washington / School of Medicine	Approved	D-022708-S
Transitions to Adulthood: Outcome Analysis Using Administrative Data Laura Schrager, M.A. Washington State Institute for Public Policy	Approved	D-031808-S
ACY-ACYF Grant (RPSC Program) Geoffrey Miller, M.B.A. Geo Education and Research	Cancelled	D-032508-S
Fostering Adolescents: A Foster Parent Perspective on Raising Adolescents in Foster Care William Bell, M.S.W. Casey Family Programs	Approved	D-032708-S
Children's Administration Practice Model Evaluation--Parent Interviews Mark Courtney, Ph.D. University of Washington / Partners for Our Children	Approved	D-032808-S
Foster Parent Support Pilot Study Maureen Marcenko, Ph.D. University of Washington / School of Social Work	Approved	D-032908-S
Looking at Follow-Up of CHET Screening Reports Kimmy Van University of Washington (graduate student)	Cancelled	D-041408-S
Fostering Hope Project Shannon Dorsey, Ph.D. University of Washington / School of Medicine	Approved	D-042508-S
Foster Care to College Partnership, Evaluating Postsecondary Outcomes for Foster Youth Laura Schrager, M.A. Washington State Institute for Public Policy	Cancelled	D-070108-S
A Study of Placement Stability in Washington State Fred Wulczyn, Ph.D. Chapin Hall Center, University of Chicago	Approved	D-070908-S
Fathers Engagement Project Carol Harper, M.P.A. University of Washington / School of Social Work	Approved	D-083008-S
Foster Care to College Partnership: Evaluating Postsecondary Outcomes for Foster Youth Laura Schrager, M.A. Washington State Institute for Public Policy	Conditionally Approved	D-110308-S
Multi-System Prevalence Study Gregg Halemba, M.A. National Center for Juvenile Justice	Conditionally Approved	D-110508-S

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

Do Medical Homes Improve Health Care Quality for Children with Special Health Care Needs? Frederick Connell M.D., M.P.H. University of Washington / Child Health Institute	Approved	D-011608-S
Primary Care Psychiatry Consultation and Training for Youth Receiving Medicaid (PAL) Eric Trupin Ph.D. University of Washington / School of Medicine	Approved	D-020108-S
Long-Term Cost Outcome of Pediatric Burn Injury Matthew Klein M.D. Harborview Medical Center	Approved	D-033108-S
Exposure to Medications and Adverse Cardiac Outcomes Frederick Connell M.D., M.P.H. University of Washington / Child Health Institute	Approved	D-040108-S
A Multi-State Study of Cancer Treatment and Outcomes Among American Indians Scott Ramsey M.D., Ph.D. Fred Hutchinson Cancer Research Center	Cancelled	D-010208-S
A Claims-Based Algorithm to Identify Incident Cases of Non-Small Cell Lung Cancer Scott Ramsey M.D., Ph.D. Fred Hutchinson Cancer Research Center	Approved	D-053108-S

Mental Health Division

Journey to Life Wellness Program Evaluation Dennis McBride, Ph.D. Washington Institute for Mental Health Research & Training	Approved	D-013108-S
QA/QI Evaluation of CFS Screening Form Aaron Hunt, M.D. DSHS / Western State Hospital	Cancelled	D-041608-S
FACT Program Evaluation Genevieve Rowe, M.S. King County / Mental Health Chemical Abuse & Dependency Services	Approved	D-062608-S
Evaluation of Washington State Wraparound Pilot Project Eric Bruns, Ph.D. University of Washington / School of Medicine	Approved	D-080408-S
Evaluation of Seattle School-Based Health Centers Eric Bruns, Ph.D. University of Washington / School of Medicine	Conditionally Approved	D-082808-S
Evaluation of the Treatment Mall at Eastern State Hospital Aja Matthews, B.A. Eastern Washington University / School of Social Work (graduate student)	Conditionally Approved	D-082908-S
Children's Mental Health Evidence-Based Practice Pilot Jim Mayfield, M.A. Washington State Institute for Public Policy	Conditionally Approved	D-102208-S

Special Commitment Center

Washington State Sex Offender Risk Assessment Initiative Rebecca Jackson, Ph.D. Pacific Graduate School of Psychology	Approved	D-041008-S
Mentally Ill Offenders: A Comparison of Commitment Standards Rebecca Jackson, Ph.D. Pacific Graduate School of Psychology	Approved	D-053008-S

DEPARTMENT OF HEALTH	Status	Study #
Community and Family Health		
WSC Impact on Economic Outcomes of Diabetes Patients on Medicaid Amira El-Bastawissi, MBCHB, Ph.D. DOH / Community and Family Health	Approved	D-022208-H
Adventist Health Study - 2 Gary Fraser, M.D., Ph.D. Loma Linda University	Approved	D-052308-H
Blinded HIV Seroprevalence Survey of Incoming Inmates in a Washington State Correctional Facility Maria Courogen, M.P.H. DOH / Infectious Disease/Reproductive Health	Approved	D-060208-H
Cancer Incidence and Cancer Morality in the World Trade Center Health Registry Mark Farfel, Sc.D. New York City Dept of Health and Mental Hygiene	Approved	D-090308-H
The Impact of Washington State Diabetes Collaborative III on Patient Economic Outcomes and Process of Care Song Wang, M.A. University of Washington /Department of Health Services (graduate student)	Conditionally Approved	D-102308-H
Youth Health Risk Survey Stacy Wenzl, M.P.H.A. Spokane Regional Health District	Approved	D-103008-H
Epidemiology and Biostatistical Component of the Pratt & Whitney Cohort Mortality & Cancer Incidence Study Gary Marsh Ph.D. University of Pittsburgh	Conditionally Approved	D-110608-H
Epidemiology, Health Statistics, and Public Health Laboratories		
Surgical Clinical Outcomes Assessment Programs David Flum, M.D. University of Washington Medical Center	Approved	D-031908-H
Association of Surgical Volume with Reoperation Rates Following Lumbar Spine Surgery in Washington State Brook Martin, M.P.H. University of Washington / School of Public Health (doctoral student)	Approved	D-040308-H
Diabetes Evaluation in Washington (DEW-IT) 2 William Hagopian, M.D., Ph.D. Pacific Northwest Diabetes Research Institute	Approved	D-052408-H
Hematopoietic Cell Transplantation - Hospital Discharge Data Linkage Study Eric Chow, M.D. Fred Hutchinson Cancer Research Center	Approved	D-061908-H
Pre-Hospital Care of the Patient with Non-Traumatic Hypotension in King County Thomas Rea, M.D., M.P.H. University of Washington / School of Medicine	Approved	D-070208-H
Long-Term Outcomes of Pediatric Out-of-Hospital Cardiac Arrest Erica Michiels, M.D. University of Washington / School of Medicine	Conditionally Approved	D-070308-H
Variation in Surgical Care for Gastrointestinal Cancers David Flum, M.D. University of Washington Medical Center	Approved	D-070608-H
Evaluation of Agricultural Related Environmental Factors Associated with Increased Risk of Gastroschisis in Washington State Sarah Waller, M.D. University of Washington / School of Medicine	Approved	D-071508-H

Campylobacteriosis Risk Factors in Dairy Counties Margaret Davis, D.V.M., M.P.H., Ph.D. Washington State University / Veterinary Microbiology	Conditionally Approved	D-101708-H
A Population-Based Analysis of Care and Outcomes for Cholecystectomy in the State of Washington David Flum, M.D. University of Washington/ Medical Center	Deferred	D-120308-H
Collective Efficacy, Migration Patterns, Crime, and Health Outcomes in Seattle Neighborhoods Ross Matsueda, Ph.D. University of Washington / Department of Sociology	Conditionally Approved	D-120808-H

Health Systems Quality Assurance

Look, Listen, and Link Curriculum Evaluation Marc Bolan Ph.D. Marc Bolan Consulting	Approved	D-060308-H
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DEPARTMENT OF LABOR AND INDUSTRIES

Status Study #

Safety and Health Assessment and Research for Prevention (SHARP)

Workplace Violence in Washington State Psychiatric Hospitals Barbara Silverstein Ph.D. Labor & Industries / SHARP	Cancelled	D-103108-L
An Evaluation of Ergonomic Process Changes in an Aluminum Rolling Plant Stephen Bao, Ph.D. Labor & Industries / SHARP	Conditionally Approved	D-121708-L
Ergonomic Evaluation of Bill Processing Jobs Barbara Silverstein Ph.D. Labor & Industries / SHARP	Conditionally Approved	D-122408-L

OTHER**

Status Study #

Evaluation of Remote Infrared Audible Signage Margaret Petrella, M.A. US Department of Transportation	Cancelled	D-072408-U
Evaluation of Remote Infrared Audible Signage Margaret Petrella, M.A. US Department of Transportation	Approved	D-111208-U
Sound Transit Evaluation of Remote Infrared Audible Signage (RIAS) Michael Miller, B.A. Central Puget Sound Regional Transit Authority	Conditionally Approved	D-121808-U

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

EXEMPT DETERMINATION REQUESTS

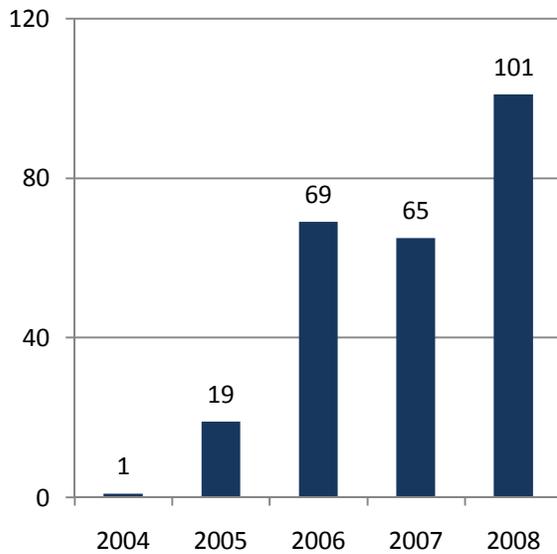


Chart: This chart demonstrates the dramatic increase in requests for exemption over the past few years, as agency staff and other researchers become aware of the exempt determination process.

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:

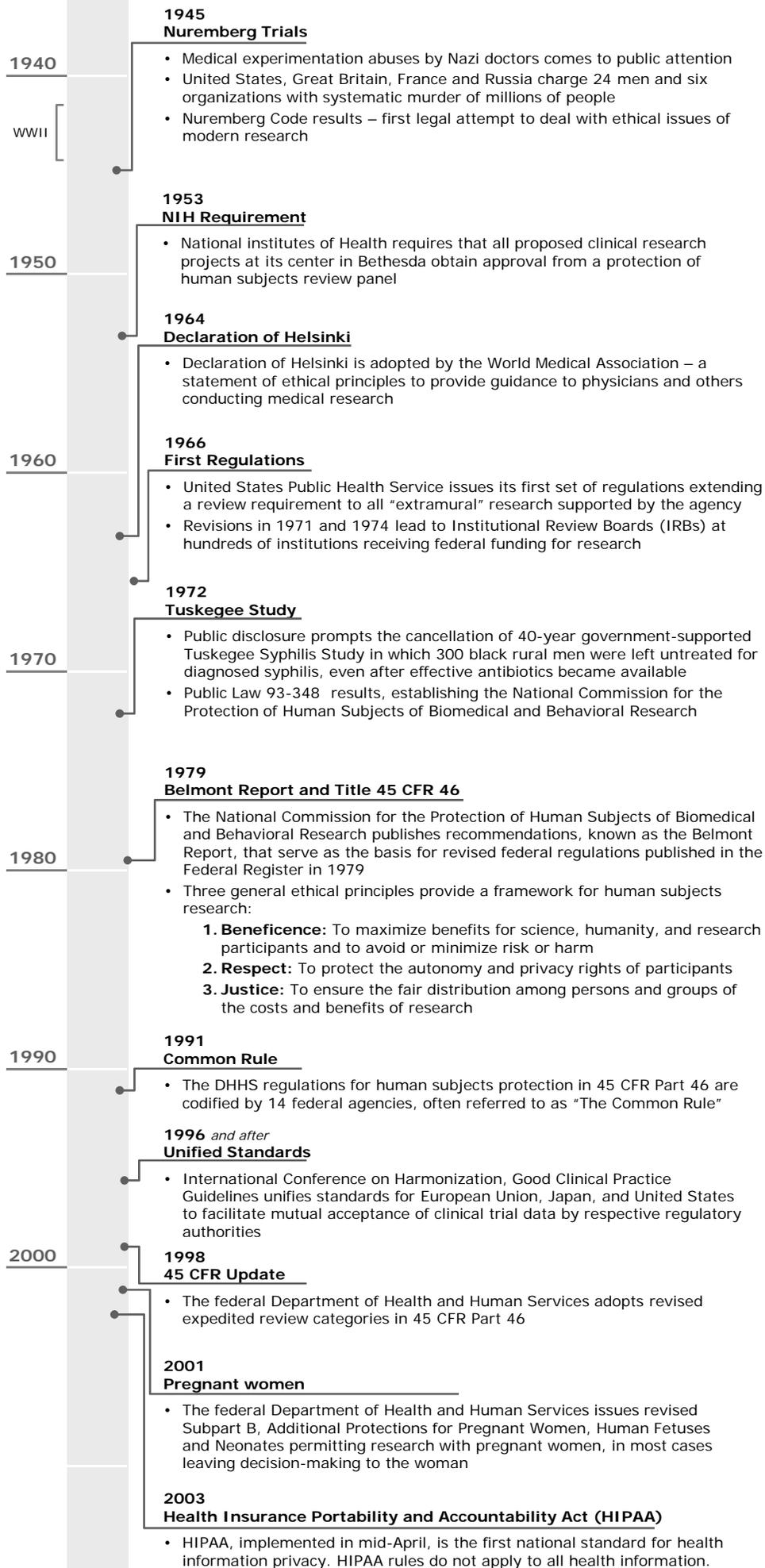
- Is the activity research?
- If it is research, does it involve human subjects?
- If the activity does involve human subjects, does it require WSIRB review?

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.

History of Human Subjects Protection IN THE UNITED STATES



SOURCE (through 1991): University of Washington, Human Subjects Division. Based on history compiled by the Fordham University Center for Ethics Education, NY.

Information after 1991 provided by DSHS Human Research Review Section

Protecting the Rights of Research Participants

Promoting the Ethical Conduct of Research



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