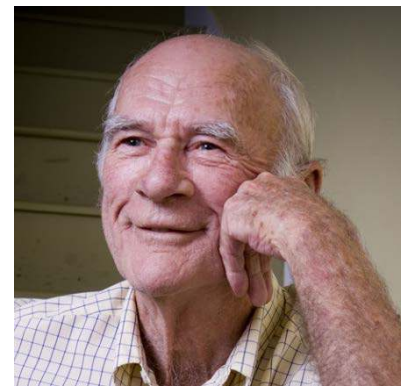




ACTIVITY REPORT 2012: Washington State Institutional Review Board

Protecting the Rights of Human Research Subjects and Promoting the Ethical Conduct of Research

August 2013



DSHS

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

Headquarters located at:
14th and Jefferson Street
Olympia, WA 98504



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Abstract: This report provides an overview of the organization, membership and work of the Washington State Institutional Review Board. It documents the legal authority for the Review Board, and describes major activities during 2012.

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), Health Care Authority (HCA), Department of Early Learning (DEL), Washington State Institutional Review Board (WSIRB).

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*Thank you for
your interest*

This Activity Report is intended to provide readers with an overview of the work of the Washington State Institutional Review Board (WSIRB) and the Human Research Review Section (HRRS), including general information about the types of activities in which the WSIRB and HRRS are engaged, research studies over which the WSIRB and HRRS have regulatory oversight, and other matters of interest to the public, research community, colleagues and our constituents. More specific information, including copies of this and past Activity Reports, may be found at our website at www.dshs.wa.gov/rda/hrrs/.

The WSIRB is a designated institutional review board (IRB) for a number of Washington state agencies, including the Washington State Department of Social and Health Services (DSHS), Washington State Department of Health (DOH), Washington Department of Labor & Industries (L&I), Washington State Health Care Authority (HCA) and (in 2013) the Washington State Department of Early Learning (DEL). The WSIRB also serves as a designated IRB for other local & state agencies and research institutions. As an IRB serving the above entities, the WSIRB is responsible for providing review, approval and oversight of research that may involve these agencies' clients, patients, wards of the State and employees or state agency personal records, in order to ensure the protection of the rights and welfare of human subjects of research.

Members of the WSIRB are drawn from among these agencies and institutions and other entities in order to provide the WSIRB with a breadth and depth of background, perspective, expertise and experience. The proper discharge of these responsibilities is required in accordance with both federal and state laws, and under the Federalwide Assurance (FWA) agreements that these agencies and institutions have with the Office for Human Research Protections, U.S. Department of Health and Human Services as a condition of federal support of their research. HRRS in the Department of Social and Health Services provides the requisite administrative and staff support for the WSIRB, including serving as members of the WSIRB. Additional support for the WSIRB and HRRS is provided by other state agencies, which includes designating and appointing agency staff to serve as members of the WSIRB.

If you have questions about this Activity Report, or about the WSIRB or HRRS, including questions about the protection of the rights and welfare of human subjects of research, do not hesitate to contact us! We may be reached at 360.902.8075 or wsirb@dshs.wa.gov. Your interest in as well as support of the work of the WSIRB and HRRS are greatly appreciated.

Sincerely,



T. Howard Stone, J.D., LL.M., C.I.P.
IRB Administrator and
Human Protections Administrator

WASHINGTON STATE INSTITUTIONAL REVIEW BOARD 2012



From Left: Margaret Frederick, Stephen Bao, T. Howard Stone, Dolf van den Heuvel, Denise Drevdahl, Alan Puckett, Hanne Thiede, Anna Y. Leon-Guerrero, Håkan Axelsson (back), Cindy Barchiesi, Grace Hong, Katrina Wynkoop Simmons (back), Marisa D'Angeli, Jovi Swanson, M. Patricia deHart, Yris Lance (new board member 2013), Lauren Jenks.

Not in picture: Adrienne Keeney, Kate Conover, Melaine Payne, Brett Parmenter, Robert D. Mootz, Kim Ambrose, Kevin Campbell and David Bonauto.

Chair

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

Executive Secretary

T.Howard Stone, J.D., LL.M., C.I.P.
Human Protections Administrator
Institutional Review Board
Administrator
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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Kim Ambrose, J.D.
Prisoner Representative
University of Washington

Marisa D'Angeli, M.D., M.P.H., F.A.A.P.
Medical Epidemiologist
DOH Communicable Disease
Epidemiology Section

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

Håkan Axelsson, M.P.A., DIHR
Non Scientist Board Member
DSHS Research and Data Analysis

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

Brett Parmenter, Ph.D.
Neuropsychology Lab
DSHS Western State Hospital

Stephen Bao, Ph.D.
Director of Ergonomics Lab - SHARP
Department of Labor & Industries

Denise Drevdahl, R.N., Ph.D.
Associate Professor
University of Washington

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

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

Grace Hong, Ph.D., M.P.P.
Research Manager
DSHS Division of Behavioral Health and
Recovery

Alan Puckett, Ph.D., M.S.S.W.
Systems Improvement Advisor
Casey Family Programs

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

Lauren Jenks, M.P.H., C.H.E.S.
Health Statistics Manager
DOH Center for Health Statistics

Jovi Swanson, M.S.W.
Policy Coordinator
DOH Policy, Legislative, &
Constituent Relations

Kevin Campbell, Dr.P.H.
Research Investigator
DSHS Division of Behavioral Health
and Recovery

Adrienne Keeney, M.S.W.
Therapist
Pasco School District

Katrina Wynkoop Simmons, Ph.D.
DSHS/PPA – Telephone Survey
Research

Kate Conover
Research Study Coordinator
University of Washington

Anna Y. Leon-Guerrero, Ph.D.
Professor
Department of Sociology
Pacific Lutheran University

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

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 five Washington State Agencies: Department of Social and Health Services (DSHS), Department of Health (DOH), Labor and Industries (L&I), Health Care Authority (HCA) and Department of Early Learning (DEL) (2013).

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.

Requirements for WSIRB Membership

Potential WSIRB members must possess the professional competence necessary to review specific research activities, such that the WSIRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. State agency and local health department staff who are involved in research, epidemiology, or clinical care serve on the WSIRB, as do faculty of local academic institutions and nonprofit agencies.

While many professional researchers and individuals with advanced degrees serve on the WSIRB, **research experience is *not* required for WSIRB membership. The federal regulations require at least one member who is a non-scientist.** The "non-scientist" requirement may be fulfilled, for example, by a member of the clergy, a social worker, a teacher, a recipient of public assistance, a former prisoner, or a librarian. Review of proposed research at a convened WSIRB meeting may only occur if at least one non-scientist member is present. The WSIRB currently has four non-scientist members.

Appointment of Board members

Recommendations for Review Board membership are solicited by the IRB Administrator from departmental administrators, Board members, and non-departmental

professional and human service agencies and organizations. Candidates for Review Board membership are submitted for consideration and formal appointment by the Secretary of DSHS or DOH.

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.

Board members also participate in reviews of proposals that pose no more than minimal risk to subjects ("expedited reviews"). These reviews are generally conducted by telephone conference between the Primary Reviewer and other reviewers as needed. Results of these reviews are reported to all WSIRB members.

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

Conflict of Interest

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

Confidentiality of Materials

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



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

2012

New Leadership



The IRB Administrator position remained vacant until April 2012. The individual selected for the position, T. Howard Stone, J.D., LL.M., C.I.P., came to the WSIRB from the Department of Defense, where he was the Research Ethics and Compliance Officer for the Army Human Research Protection Office. Mr. Stone visited with Review Section staff and agency managers in early and in late April, to lay the groundwork for the transition. Mr. Stone assumed leadership of the HRRS and WSIRB full-time in June. His vision and priorities for the DSHS Human Research Review Section and for the WSIRB will shift the focus to conducting reviews in tandem with the nature and scope of the risk to subjects in a given protocol, consistent with the proposed changes in the federal regulations governing human subjects protection (see page 11). He will also emphasize transparency in WSIRB operations and decisions with investigators, the state agencies, and external parties. The third priority is education and training of WSIRB members and staff.

Going Electronic!

In May, the Review Section put out a Request for Bids for an electronic protocol management system for tracking, reviewing, and oversight of submissions to the WSIRB. The current Access database was transferred to the new system and Review Section staff fine-tuned coding, structure, and templates. Most application appendices are incorporated into the main form, and are no longer separate documents. There may be a transition period in which both paper and electronic

submissions will be accepted. WSIRB members and staff will complete training sessions on the new system, with dates to be determined. The current Access database will be run concurrently with the new system for several months, to ensure smooth operations.

The Review Section is also revising procedures to streamline the workload and amount of paperwork. Some studies that now require full committee continuation review may be moved to expedited review if they pose no more than minimal risk to subjects.

Appreciation



Hanne Thiede, DVM, MPH, completed her term as WSIRB Chair in December 2012. During her 5-year tenure as Chair, Dr.

Thiede brought structure, wisdom, and fairness to WSIRB discussions and decisions. A celebratory lunch was held in Dr. Thiede's honor in January 2013; Dr. Thiede will remain a WSIRB member.



Dolf van den Heuvel, PhD, and Melanie Payne, MPH both attained Distinguished Member status, having served on

the WSIRB for 10 years. We appreciate their dedication to human subjects protection and their many contributions to the Review Board over the years. Dr. van den Heuvel and Ms. Payne will continue to serve on the WSIRB.

David Bonauto, MD, MPH, resigned from the WSIRB in February 2012. We greatly appreciate his

thoughtful approach to human subjects reviews over the nine years he served as a valued member.

Kevin Campbell, DrPH, resigned in July. Since June 2000, when he was appointed to the WSIRB, Dr. Campbell was Primary Reviewer on 40 projects. Dr. Campbell's expertise in public health and substance abuse issues has been an asset to Board deliberations.

Adrienne (Annie) Keeney, MSW, was appointed to the WSIRB in September 2009 while she was an MSW candidate at Eastern Washington University. After 3 years on the WSIRB, Ms. Keeney resigned in July to pursue a doctorate in social work.

Kate Conover was appointed to the WSIRB in January as a "non-scientist" with previous volunteer and research assistant experience at the University of Washington. Ms. Conover will pursue a doctorate in psychology.

New WSIRB Members:



Marisa D'Angeli, MD, MPH, is a pediatrician and Medical Epidemiologist in DOH Communicable Disease

Epidemiology. Dr. D'Angeli obtained her MD at the University of California Davis and her MPH at the University of Washington.



Lauren Jenks, MPH, CHES, is Health Statistics Manager in the DOH Center for Health Statistics. She received her MPH at Temple

University and has been employed at DOH for over 10 years.



Grace Hong, PhD, is Epidemiological Prevention Research Manager in the DSHS Division of Behavioral Health and Recovery. She obtained her doctorate in public policy and research methodology from the University of Maryland.

Congratulations



Lilly Moneer, CIP, Compliance Coordinator in the Review Section, graduated from the Evergreen State College in June 2012, with an emphasis in psychology.



Lilly Moneer and Maggie Frederick attended the national IRB

conference in San Diego in early December. The conference is sponsored by Public Responsibility in Medicine and Research.



Jovi Sanchez Swanson, MSW, was appointed as a non-scientist member in November. Ms. Swanson holds an MSW from the

University of Michigan and is actively involved in diversity issues.

Education and Training

Eight Review Board members attended an all-day Regional IRB Education Conference sponsored by the Northwest Association for Biomedical Research in Seattle on April 24, 2012.

LEGAL AUTHORITY

In accordance with Federal and State laws, State agency policies and under applicable agreements, the WSIRB has authority to provide review, approval and oversight of research involving human subjects that may involve: state agency clients, patients, wards, employees or state agency personal records.

Washington State Agency Policy on the Protection of Human Research Subjects extends the federal regulations for human subject protections to all research involving human subjects in the departments' jurisdiction, regardless of the funding source.

FEDERAL REGULATIONS

- 45 CFR, Part 46 – Protection of Human Subjects
- 45 CFR, Part 164 – HIPAA Privacy Rule

STATE STATUTES AND RULES

Revised Code of Washington:

- RCW 42.48 – Release of Records for Research
- RCW 70.02 – Medical Records, Health Care Information Access and Disclosure

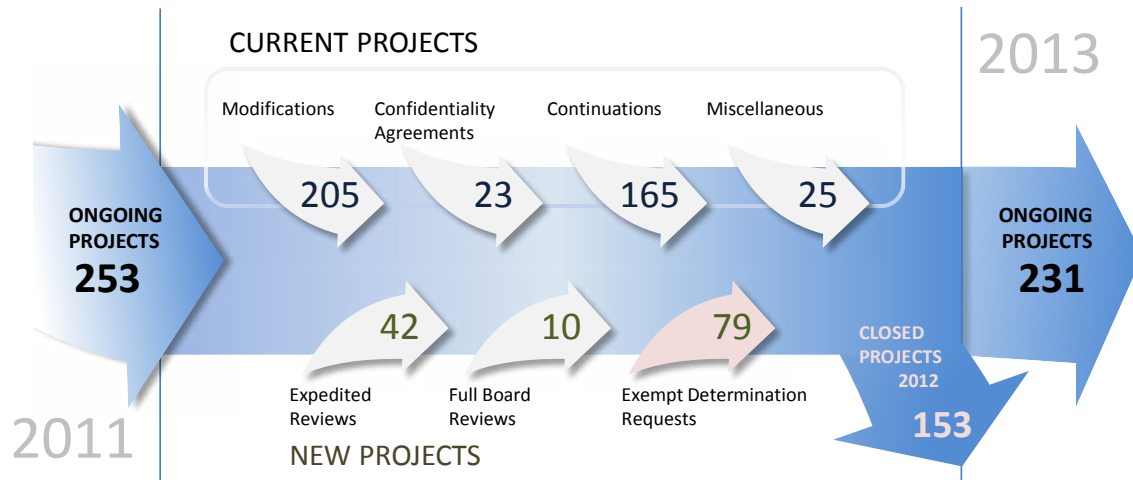
Washington Administrative Code:

- WAC 388-04 Protection of Human Research Subjects

STATE AGENCY POLICIES

- DSHS Administrative Policy 12.01
- DOH Administrative Policy 03.001
- L&I Administrative Policy 9.43
- HCA Administrative Policy 1-12

WSIRB/HRRS WORKLOAD VOLUME DURING 2012



CURRENT PROJECTS

Modifications (205)

Modifications refer to any changes to a study, and may include for example adding or removing research staff, adding new or deleting previously-approved study aims or activities, or changes to study samples or instruments. Modifications may be made at the direction of the WSIRB or initiated by the study team. Study modifications generally may not be made without WSIRB review and approval.

Confidentiality Agreements (23)

Confidentiality Agreements refer to legally binding agreements between researchers and state agencies that are required for studies for which researchers propose to acquire state agency individually identifiable personal records without obtaining informed written consent from individuals (or their legally authorized representatives) about whom the records may pertain. These Agreements prohibit re-disclosure for any purpose by researchers of any records to which the Agreements apply. Unauthorized disclosures are a gross

misdemeanor and may result in a civil penalty against researchers of not more than \$10,000 for each violation. Pursuant only to WSIRB approval, these Agreements are prepared and staffed by the HRRS through applicable state agencies.

Continuations (165)

Continuations refer to WSIRB reviews of on-going studies whose periods of WSIRB approval, which may not exceed one year, are set to expire and for which studies researchers plan to carry on. All studies must be reviewed by the WSIRB at least once each year. Criteria for WSIRB approval of continuing studies are the same as applied to initial review of research.

Miscellaneous (25)

This refers to all other actions submitted to or taken by the HRRS and WSIRB, and may include for example reports of adverse events or other unanticipated problems involving risks to subjects or others (UPIRTSO), deviations to WSIRB-approved procedures, and suspensions or terminations of research.

ONGOING & NEW PROJECTS

In the beginning of 2012 the Washington State Institutional Review Board had 253 ongoing projects. During 2012 there were 131 new projects submitted for review. During the year 153 projects were closed, and at the end of December 2012, there were 231 ongoing projects.

Expedited Reviews (42)

Review of proposed research by the IRB Chair or a designated voting member or group of voting members, rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [45 CFR §46.110].

Full Board Review (10)

Review of proposed research at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

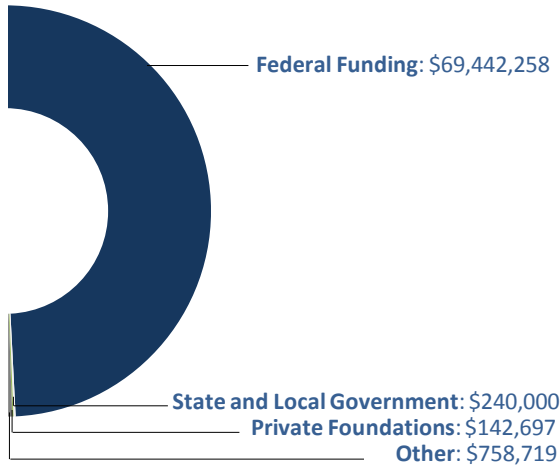
Exempt Determination Requests (79)

Some research projects using human participants raise no substantial risk to subjects. To qualify for an exempt review process, research must involve no more than **minimal risk** (summarized as no greater risk than that encountered in everyday life).

NEW PROJECTS REVIEWED

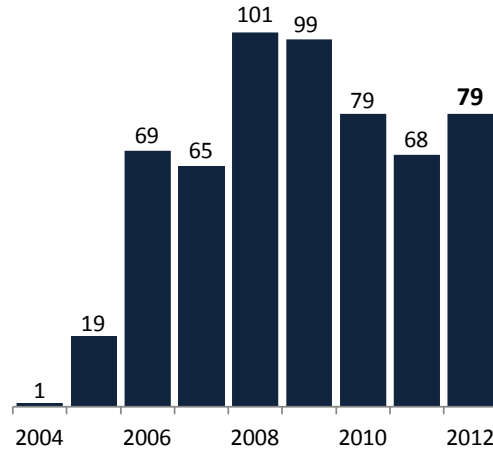
FUNDED PROJECTS TOTAL \$70,583,674

Proposals Reviewed (Expedited and Full board): 52



The chart to the left shows **the source of funding for new studies reviewed** in calendar year 2012. Among the 52 projects reviewed during 2012 that had been awarded project-specific funding, the vast majority were funded by various branches of the federal government.

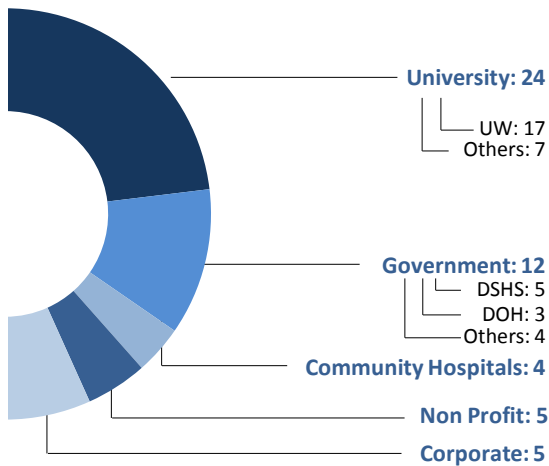
EXEMPT DETERMINATION REQUESTS (79)



This chart shows a continuing trend of requests for exemption over the past few years, as agency staff and other researchers become aware of the exempt determination process.

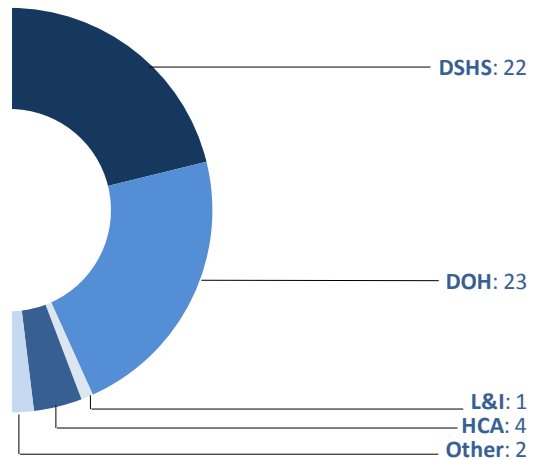
During 2012 fourteen percent of the 79 exempt requests were determined to be research that was not exempt.

RESEARCHER AFFILIATION (52)



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

STATE AGENCY (52)



The Department of Social and Health Services and Department of Health together accounted for 86.5% and Department of Labor and Industries, Health Care Authority and others for 13.5% of all new proposals reviewed during 2012.

ASK THE HRRS



Q: I have approval from my institution's IRB. Do I need to submit to the WSIRB, too?

A: You might. If a study involves disclosure of identifiable agency records, such as the cancer registry, Medicaid records, confidential birth records, or other administrative records held by DSHS, DOH, DEL, HCA or L&I, WSIRB review would be required. If you plan to contact agency clients with the assistance of the state agency, the study would require WSIRB review. The WSIRB may only need to review the component(s) in its jurisdiction, rather than the entire study. Call the DSHS Human Research Review Section to discuss the details of your project and to find out how to proceed at 360.902.8075.

Q: Why does the WSIRB require continued training in human subjects' protection?

A: Research is an ever-evolving enterprise, and it is imperative that researchers and their staff remain current on best practices for human subjects protection. Federal regulations, state laws, and agency policies change over time. So, too, do the issues that confront researchers when conducting research. Novel approaches, such as research using social media or the internet or DNA repositories, may pose unforeseen risks to subjects and to third parties. Training in human subjects protection ensures that the rights and welfare of subjects continue to be a priority. As research evolves, potential risks/harms to subjects may also change. Researchers, and IRBs, must remain current in their knowledge of human subjects' protection.

Q: Why does the WSIRB consider research design as part of its review if a study has been federally funded and already undergone scientific peer review?

A: Federally funded studies that have been subject to peer review suggest that the studies are both competitive and have demonstrated scientific merit. Researchers are encouraged to provide the WSIRB with copies of summary statements or other documentation

of scientific review with their Applications for WSIRB Review. While informative, prior scientific reviews are not dispositive to the WSIRBs' review determinations with regard to research design, as state law requires the WSIRB to also consider a study's design in light of the agency's program concerns; access to and availability of state agency records, where applicable; burden upon state resources to accommodate study activities; and access to and recruitment of state agency clients, patients, wards or employees as study subjects, as needed. Unresolved, these issues may serve to undermine achievement of study objectives or timely and successful completion of research. When making their scientific review decisions, peer reviewers, unlike the WSIRB, are unlikely to have the requisite insight into these important considerations with research design implications. The WSIRB will convey any concerns about these matters to researchers so that study purposes can more reasonably be accomplished.

Q: How are conflicts of interest information used by the WSIRB?

A: The WSIRB must decide how to minimize or eliminate such financial and non-financial conflicts, if necessary, including how, if at all, prospective human subjects or persons already enrolled as subjects must be informed about these conflicts during initial and continuing consent. Different federal and state laws, as well as Washington state agency policies, have conflicts of interest requirements, and the WSIRB administers many of these requirements. Researchers' institutions have their own requirements that must be followed.

Q: I am an agency employee. Do I need IRB review for internal research?

A: Yes. Human subjects review is required for *any* research conducted by the five state agencies (DSHS, DOH, HCA, L&I and DEL) or contracted out to another entity, and which involves state agency clients, patients, wards, employees or their state agency records as human subjects.

Q: I already have access to clients/records because I work at the agency. Do I still need WSIRB review for a student project?

A: Yes. Research for student projects (thesis, dissertation, or class projects) are considered *personal* use of state agency resources, records, or access to clients. These projects go beyond normal work duties and would be conducted for *personal* reasons (e.g., completing a degree or course requirements). If the project would involve DSHS/DOH/L&I/HCA/DEL records, clients, facilities, or equipment, or agency employees as subjects, WSIRB review would be required.

Q: My agency is starting a demonstration program or pilot project. We plan to evaluate it to find out if the program is cost-effective and improves client outcomes. Does the evaluation require WSIRB review?

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

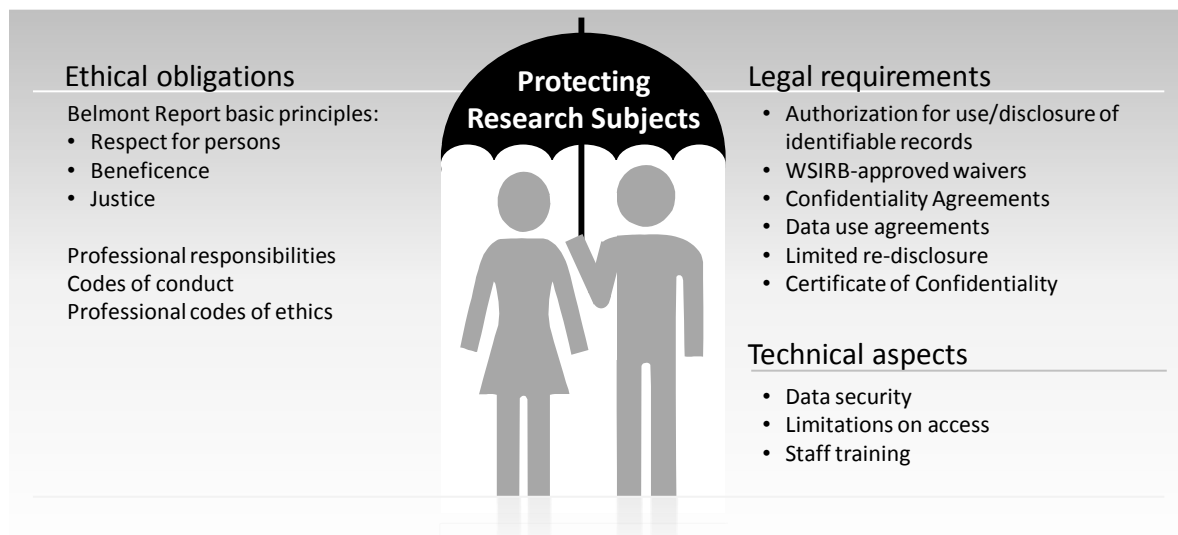
Q: May I request exemption so I can publish or present my results?

A: If you have already begun the activity, or if you have reached the stage of publication or presentations at conferences, an exempt determination may not be granted. All requests must be submitted before you begin the work. Exemption cannot be granted retroactively; journals requiring IRB review may not accept your article for publication.

Q: How do I find out if my project is research that requires WSIRB review, or something else?

A: If you are not sure if a proposed activity is research, program evaluation, quality improvement, or something else, call HRRS at 360.902.8075 to discuss your plans. HRRS may advise you to submit an Exempt Determination Request for review. You will receive a written response within a few days that informs you if the activity is not considered research, or if it is research that is exempt from WSIRB review.

Human subjects framework for protecting confidentiality



Confidentiality refers to the protection of information about human research subjects.

SPOTLIGHT ON SELECTED STUDIES

The following section spotlights proposals that were either reviewed or closed during 2012, by agency. We hope this will provide a picture of the broad spectrum of research reviewed by the WSIRB, the research methodologies used, and some of the key findings that may have implications for public policy and public service programs. These studies were chosen at random.

DSHS – Department of Social and Health Services



“Assessing the Costs and Benefits of Public Guardianship Services”

Principal Investigator: Mason Burley, M.P.A., Washington State Institute for Public Policy.

The goal of this project was to study the costs and savings to the state of a public guardianship program for persons who are legally incapacitated from making their own financial and personal decisions, but for whom adequate guardianship services through traditional mechanisms were not available. The program was piloted in a number of counties across the state. Researchers found that over time public guardianship clients did experience savings in terms of residential costs, reductions in needed personal care and improvements in self-sufficiency. However, it was not clear how precisely public guardianship services contributed to these positive outcomes.

“Workforce Initiative Fund Housing and Employment Navigator Model Program Evaluation”

Principal Investigator: Marc Bolan, Ph.D., Marc Bolan Consulting.

The primary objective of this study is to evaluate an innovative intervention program that is intended to provide homeless families with training and skills considered crucial for securing employment and staying employed. The study is funded by the U.S. Department of Labor. The study involves examining how enhanced collaborative activities among housing and other social services providers across Washington may serve to improve homeless families' career development, employment and housing stability. As part of this study, state agency records are used to help inform some of the intervention outcomes.

DOH – Department of Health

“Pyrethroid Exposure Survey and Testing (PEST) Project”

Principal Investigator: Juliet van Eenwyk, Ph.D., Washington State Department of Health.

This study is evaluating pyrethroid exposures in licensed indoor and structural Pest Control Operators (PCOs) in Western Washington. Study results will be used to strengthen training and education for PCOs. The research team will also determine whether pyrethroid biomonitoring can be a practical and useful tool for future monitoring of pesticide applicators. Subjects will collect three urine samples following a work shift when they used pyrethroids and complete a survey about their work practices that day, such as their use of protective gear, their hand-washing practices and questions about other potential non-occupational sources of pyrethroid exposure.

“Mechanisms for Racial Disparity in Preterm Birth (A Better Chance Project)”

Principal Investigator: Jane Hitti, M.D., M.P.H., University of Washington, Department of Obstetrics and Gynecology.

This five-year population-based prospective cohort study evaluated the relative contributions to preterm birth of lower genital tract infection, maternal stress and a genetic predisposition to an enhanced immune response among African American and white women in King County, Washington. Birth records were used to identify a sample of eligible women. The researchers found few significant differences between women with a prior preterm birth and those with a prior term birth with respect to demographics, life stressors, social support, perceived stress, vaginal infections and sub-clinical endometritis. They did find important interactions between racial group, income (adjusted for number of dependents), stressful life events and pro-inflammatory activation. With stratification by racial group, the associations between very low income, stressful life events and perceived stress persisted among white women but not among African American women, suggesting that a higher income level may be less protective for stress among African American women. These analyses have also highlighted some methodological limitations in the assessment of racial identity and the experience of racial discrimination.

"The Effects of Economic Recession on Traumatic Injury Patterns"

Principal Investigator: Patricia Ayoung-Chee, M.D., Harborview Injury Prevention and Research Center.

According to the National Bureau of Economic Research, the last two economic recessions were from March 2001 to November 2001 and December 2007 to June 2009. The researchers analyzed records from the Washington State Trauma Registry, from January 1995 to December 2010, to evaluate changes in frequency and distribution of motor vehicle collisions, falls and intentional injuries before, during and after the recessions and to evaluate the pattern of transfers from lower-level and non-trauma hospitals to higher level trauma hospitals. Upon initial analysis of data, using publicly available reports and timing of the economic recession and gasoline prices, no association between the economic recession and motor vehicle collisions in Washington State were observed.

L&I – Department of Labor and Industries

"Pilot Study of Risk Factors for Heat-Related Illness in Agricultural Workers"

Principal Investigator: June T. Spector, M.D., M.P.H., University of Washington Department of Environmental and Occupational Health Sciences.

This research is using worker's compensation claims from the agriculture, forestry, and fishing sectors to evaluate heat-related injuries. Claims incidence rates, costs, severity, and potential risk factors will be evaluated, along with Division of Occupational Safety and Health violations of the Agriculture Heat Rule.

HCA – Health Care Authority

"Comparison of Methods to Identify Children with Special Health Care Needs (SHCN) in Washington Medicaid Data"

Principal Investigator: Mary Lawrence Cawthon, M.D., M.P.H., DSHS Research and Data Analysis Division.

The purpose of this project is to develop a methodology to accurately identify children with complex health care needs using hospital discharge and/or Medicaid records. This research will identify an appropriate eligible patient population to which care coordination quality measures can be applied, and stratify quality measures by complexity of health care conditions.

"Youth Who Incur High Mental Health-Related Costs to the State of Washington"

Principal Investigator: Debra Srebnik, Ph.D., King County Mental Health and Chemical Abuse and Dependency Division.

The main goal of the research is examine predictors and reasons for high mental health-related costs among children and youth in King County who are and are not in foster care.



"Drug Use and Fracture Rate in Women with Developmental Disabilities who Received Fee for Service Medicaid in Washington State during 2002"

Principal Investigator: Kathleen Watson, Ph.D., R.N., University of

Washington Center on Human Development and Disability.

The purpose of this project was to evaluate any association between incidence of osteoporotic fractures and use of depot medroxyprogesterone acetate (DMPA) and/or anti-epileptic drugs (AEDs) among women and girls with developmental disabilities who received fee-for-service Medicaid in Washington State during 2002. It was concluded that the use of either AEDs or DMPA by women with developmental disabilities is associated with significantly increased incidence of fracture. Women and girls who have developmental disabilities may be poor candidates for DMPA use owing to increased risk of fractures. Further research is indicated to determine the specific risks profile of DMPA for this population, to explore alternative means of managing significant menstrual problems and contraceptive needs in this population and to screen current and previous users of DMPA and chronic users of AEDs for osteoporosis risk, regardless of age.

Proposed Revisions to Federal Regulations for Human Subjects Protection

The Office of the Secretary of the Department of Health and Human Services issued an Advance Notice of Proposed Rule Making (ANPRM) in July 2011. The ANPRM, if adopted, would make significant changes in the federal regulations governing human subjects protection. Regulations that may change include 45 CFR Parts 46, 160, and 164, and 21 CFR Parts 50 and 56. The current human subjects regulations have been in place since 1991.

These changes are proposed in order to keep abreast of changes in research volume, focus, and complexity. As research has expanded out of academic institutions and become international in scope, new regulations may be required. New technologies have also expanded research methodology, such as use of the Internet, biobanking, and use of identifiable electronic records. The Office for Human Research Protections states that the changes under consideration "would ensure the highest standards of protections for human subjects involved in research, while enhancing effectiveness of oversight." The revision would extend federal regulatory protections to apply to all research conducted at U.S. Institutions receiving funding from the Common Rule agencies.

Five of the most sweeping changes to the federal regulations are summarized below. The general focus of these changes is to calibrate the level of review required for a given research project to the degree of risk it would pose to subjects. Under this paradigm, if informational risks (privacy, confidentiality) are minimized, the study could move through the review and approval process in a timely, less resource-intensive manner. IRBs could focus the majority of their resources and time on research that poses greater than minimal risk.

1. Require data security and information protection standards for identifiable research information and adopt rules prohibiting re-identification of the information.

The proposed regulations would adopt the definitions used in the HIPAA Privacy Rule for individually identifiable, limited datasets, and de-identified information. The WSIRB generally applies the HIPAA standards of de-identification to all datasets requested for research.

2. Revise the requirement for continuation review.

Proposals that qualified for expedited review would no longer be required to seek continuation approval under the ANPRM. If the initial review of a study was conducted by full committee review, continuing review would not be required if research activities were limited to data analysis or routine clinical follow-up of subjects. Exceptions could be made only if the IRB specifically required continuation review and provided a justification for greater oversight. The exception could be used for both expedited and full committee reviews.

3. Require regular updates to the categories of research that qualify for expedited review.

This change in the regulations would also streamline submission requirements for research that qualifies for expedited review.

4. Revise the criteria for exemption from human subjects protection requirements.

Under the ANPRM, investigators would be able to file a one-page summary of their proposed research to inform the IRB of their plans. Routine review by IRB staff would not be required, but discouraged. IRBs could perform random retrospective audits, to ensure that such studies are exempt and conform to the new regulations.

The proposed regulations would also exempt all studies involving educational tests, interviews, focus groups, and similar procedures if subjects were competent adults. The data security standards would be required in order to qualify for exemption.

Secondary use of identifiable data or biospecimens in identifiable form would be permitted as exempt research if the data or specimens were collected for non-research purposes and certain consent requirements had been met. Under this revised exempt category, researchers could retain identifiers and could prospectively collect these data or biospecimens. The current exemption applies only to retrospective research.

5. Generally require signed consent for research use of any biospecimens collected for clinical purposes.

Patients could sign a standardized consent form to allow future research on biospecimens. The consent form could broadly allow any/all use of specimens, or could be formatted so that patients could choose which uses to permit. The general rule would be that patients must give such consent, although it need not be study-specific and could cover open-ended future research. If such consent were in place, the study may qualify for exemption under the revised regulations.

The ANPRM was open for public comment until October 26, 2011. Review Section staff were not able to provide written comments to HHS, given the increased WSIRB workload. However, some proposed revisions to the regulations do not appear consistent with state statutes for disclosure of identifiable records (RCW 42.48) or the *Washington State Agency for the Protection of Human Research Subjects*. We understand that there will be additional opportunities to comment on the proposed regulations, at which time we hope to provide input.

As of the publication of this Report, the ANPRM continues to circulate among federal agencies, and has not yet been finalized.

The ANPRM may be accessed at <http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html>

History of Human Subjects Protection IN THE UNITED STATES

1940

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

1953

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

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

1960

1972

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

1970

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



1980

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”

1990

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.

2000

2011:

Secretary of the Department of Health and Human Services Issues Advance Notice of Proposed Rule Making

The proposed rule would make significant changes in the federal regulations governing human subjects protection. The rule would calibrate the level of review to the degree of risk it poses to subjects. If informational risks (privacy, confidentiality) are minimized, the study could move through the review and approval process in a timely, less resource-intensive manner. IRBs could focus the majority of their resources and time on research that poses greater than minimal risk. See page 11.



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

Image source:

Nurember: law.harvard.edu

Tuskegee: The National Archives

2010

2012:

Public Health Service Revised Regulations on Financial Conflict of Interest

- Institutions that receive Public Health Service funds are required to implement new procedures for the review, management and reporting of significant financial conflicts of interest.
- New regulations lower the threshold to \$5,000 for disclosure of compensation for services or equity interest in a publicly traded company, with a \$0 threshold for disclosure of equity in a non-publicly traded company.
- Investigators must disclose all significant financial interests related to their institutional responsibilities, not just those related to the PHS-funded research.
- Investigators must complete mandatory training before undertaking PHS-funded research.
- The regulations took effect September 26, 2011; compliance was required no later than August 24, 2012.

**Protecting the Rights of
Human Research Subjects**



**Promoting the Ethical
Conduct of Research**

For more information, please
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