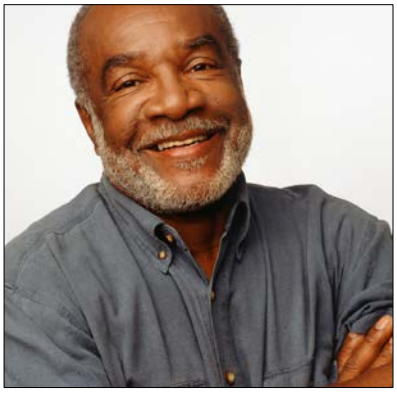
ACTIVITY REPORT 2013: **Washington State Institutional Review Board**

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

October 2014



Washington State Department of Social & Health Services

Washington State Department of Health

Washington State Department of Early Learning

Washington State Health Care Authority

Washington State Department of Labor & Industries

DSHS

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Department of Social and Health Services

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Information about this Publication

Title: Washington State Institutional Review Board, January – December 2013

Abstract: This report provides an overview of the responsibilities, organization, and membership of the Washington State Institutional Review Board (WSIRB). The report also documents the legal authority for the Review Board, and describes the WSIRB workload and major activities during 2013.

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 (DSHS), 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).

Category: Institutional Review Board Activities

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CONTENT

Letter from the IRB Administrator

This Activity Report is intended to provide our constituents and readers with an overview of the 2013 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 on our website at www.dshs.wa.gov/rda/hrrs/.

The WSIRB is a designated institutional review board (IRB) for a number of different Washington state agencies, including the Washington State Departments of Early Learning (DEL), Health (DOH), Social and Health Services (DSHS), Health Care Authority (HCA) and Labor & Industries (L&I). 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 the requisite regulatory review, approval and oversight of research that may involve these state agencies' clients, beneficiaries, patients, wards and state agency employees or these individuals' state agency personal records, in order to ensure the protection of the rights and welfare of human subjects of research.

WSIRB members are drawn from among these agencies as well as other institutions and entities. Our members provide the WSIRB with a breadth and depth of diverse but highly relevant scientific, disciplinary and professional background, perspective, expertise and experience. The appropriate discharge of its review and oversight responsibilities and the WSIRB's diversity and expertise is required in accordance with both federal and state laws, and under the Federalwide Assurance (FWA) legal agreements that each of these agencies and institutions have entered into with the Office for Human Research Protections of U.S. Department of Health and Human Services as a condition of applying for and receiving federal support of their research. HRRS in the Department of Social and Health Services provides the regulatory required administrative, professional and technical support for the WSIRB, including serving as members of the WSIRB. Support for the WSIRB and HRRS is provided by other state agencies, which includes designating and appointing agency staff to serve as WSIRB members.

If you have questions about this 2013 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 are happy to provide guidance, consultation and information. 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 2013

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, Lauren Jenks. **Not pictured:** Kim Ambrose, Robert D. Mootz, and Melanie Payne.

Chair
Katrina Wynkoop Simmons, Ph.D.
Research Scientist
Foundations for Healthy Generations

Executive Secretary
T. Howard Stone, J.D., LL.M., C.I.P.
IRB Administrator
DSHS Human Research Review Section and Human Protections Administrator for DEL, DOH, DSHS, HCA and L&I

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

Members (Regular and Alternates)

Kim Ambrose, J.D.
Senior Law Lecturer
University of Washington
Prisoner Representative

Håkan Axelsson, M.P.A., DIHR
Business Analyst/Web Communications
DSHS Research and Data Analysis

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

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

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

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

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

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

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

Yris Lance, M.A.
Community Relations Liaison
Washington State Board of Health

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

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

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

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

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

Hanne Thiede, D.V.M., M.P.H.
Lead Epidemiologist
Public Health-Seattle & King County

Dolf van den Heuvel, Ph.D.
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 affiliations and professions to promote complete and adequate review of research activities conducted within the jurisdiction of the Washington State Agencies served: the Washington State Departments of Early Learning (DEL), Health (DOH), Social and Health Services (DSHS), Health Care Authority (HCA) and Labor & Industries (L&I).

In accordance with federal regulations, Washington State agency policies and the WSIRB procedures, 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, program and service delivery and clinical care serve on the WSIRB, as do faculty of local academic institutions and non-profit agencies.

While many 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, teacher, recipient of public assistance or family member, current or former prisoner, lay person or 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 five non-scientist members.

Appointment of Board members
Recommendations for Review Board membership are solicited by the IRB Administrator from departmental administrators, Board members, non-departmental professionals and other human service agencies and organizations. Candidates for Review Board membership are submitted for consideration and formal appointment by the State agency leadership.

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 up to 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 and related materials 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 or HRRS staff.

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

WASHINGTON STATE INSTITUTIONAL REVIEW BOARD ACTIVITIES

2013

2013 brought many changes to the WSIRB and to HRRS, from the highest levels of agency leadership to the daily operations of the WSIRB and the Human Research Review Section.

Changes in Agency Leadership

Washington Governor Inslee appointed Kevin Quigley, JD, LLM, as Secretary of DSHS and Joel Saks, MPA, as Director of L&I in January 2013. Dorothy Frost Teeter, MHA, was appointed Director of the Health Care Authority in February and John Wiesman, DrPH, MPH, as Secretary of DOH. The appointment of new state agency directors or secretaries must be reported pursuant to each institution's Federalwide Assurance (FWA) with the Office of Human Research Protections of the U.S. Department of Health and Human Services.

David Mancuso, PhD, was appointed Executive Director of the DSHS Research & Data Analysis Division (RDA, in which HRRS is located) in September 2013, replacing Ron Jemelka, PhD, who retired in August. Dr. Mancuso holds a PhD in economics from Stanford University and has led several innovative projects within RDA over the past several years focusing on service delivery and outcomes for DSHS clients. Alice Huber, PhD, was appointed Deputy Director of RDA in October. Dr. Huber has been with DSHS for over 8 years, most recently as Chief of Decision Support and Evaluation, Division of Behavioral Health and Recovery. Review Section staff now report to the Deputy Director.

Barbara Silverstein, PhD, Human Protections Administrator (HPA) for L&I, retired in November, and T. Howard Stone replaced her as the HPA for L&I.

Streamlining the Workload

The WSIRB has been moving select Continuation Approval Requests from the full committee to the expedited review pathway. Federal regulations provide latitude for utilizing these procedures to ease the regulatory burden. Decisions about which particular studies may be reviewed under the expedited review procedure are made as each study comes up for continuation review.

Another change is listing only expedited CARs that have been *approved* on each meeting agenda; rather than all studies due for continuation review. The new procedure conforms to 45 CFR 46, section 46.110(c): "Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure."

Collaboration

In March, the Whatcom County Health District entered into FWA with the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services, and named the WSIRB as its IRB of record. FWAs are legally binding arrangements under which an institution provides to federal agencies assurances of the institution's compliance with federal laws pertaining to human subjects protection. FWAs are required under federal law as a condition of receiving federal support for research. Each institution with an FWA must also designate an IRB, registered with OHRP, such as the WSIRB, that has responsibility for review, approval and oversight of human subjects research.

DSHS and HIPAA

DSHS changed its designation from a uniform covered entity to a covered entity whose business activities include both covered and non-covered functions in accordance with the HIPAA Privacy Rule. This change affects some procedures for WSIRB review of research under DSHS jurisdiction, particularly in terms of DSHS records for research. For waiver of authorization and other requirements pertaining to use of purposes of de-identification, the removal of the 18 identifiers would no longer be categorically required for records derived from non-covered DSHS functions.[1]

Appreciation

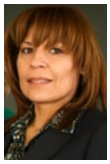
Hanne Thiede, DVM, MPH

WSIRB members held a celebratory lunch in honor of Dr. Thiede's five years of service as Board Chair, which she completed in December of 2012. We appreciate Dr. Thiede's leadership, collegiality and guidance during her tenure as Chair. Dr. Thiede continues as a WSIRB member.

New WSIRB Chair

Katrina Wynkoop Simmons, PhD, was appointed the new WSIRB Chair. Dr. Simmons has been a WSIRB member since July 2005 and brings many years of research and IRB experience to her new role. Her appointment follows an update to the WSIRB Procedures Manual allowing greater flexibility in appointing a WSIRB Chair; previously individuals not affiliated with state agencies could not serve as Chair. A Vice Chair position is being considered to allow a current member to assume Chair duties when the Chair cannot be present.

New WSIRB Members:



Yris Lance, M.A., was appointed to the WSIRB in February 2013 as a non-scientist member. Ms. Lance works as a Community Relations

[1] See the National Institutes for Health page: http://privacyruleandresearch.nih.gov/pr_08.asp for a list of these identifiers.

liaison for the Governor's Interagency Council on Health Disparities, for the Washington State Board of Health.

Marisa D'Angeli, MD, MPH, and **Lauren Jenks, MPH**, were each reappointed to three-year terms beginning in March 2013. In September, four WSIRB members were renewed for another term, the length of which varies by the individual: Cindy Barchiesi, PharmD, Grace Hong, PhD, Dolf van den Heuvel, PhD, and Robert Mootz, DC. The WSIRB memberships of M. Patricia deHart, ScD, and Jovi Swanson, MSW, were renewed for three years, through December 31, 2016 and November 30, 2016, respectively. Dr. deHart has been a WSIRB member since January 1999; Ms. Swanson has completed her initial one-year appointment.

Status of the Electronic Protocol Management System (EPMS)

In 2012, the Review Section put out a Request for Proposals for an electronic protocol management system for tracking, reviewing, and oversight of submissions to the WSIRB. Testing, internal migration and development of related procedures should be completed in 2014, with a "go-live" date planned for January 2015.

Congratulations

Lilly Moneer was promoted to Review Coordinator, and passed the rigorous Certified IRB Professional (CIP) exam in March 2013. The CIP exam is administered by the Council for Certification of IRB Professionals (CCIP) under partnership with the Public Responsibility in Medicine and Research (PRIM&R) professional organization. All HRRS review and compliance staff are now credentialed as Certified IRB Professionals. Ms. Moneer transitions to WSIRB membership in 2014.

New Review Section Staff

Linda Long Weaver, MEd, joined the Review Section in September. Ms. Weaver earned her degree from the School for International Training in Brattleboro, VT. She has been a data and IT specialist at RDA for 10 years and a Research Analyst at RDA prior to that. Her work will focus on publications, web and database development and administration, as well as testing and support for the EPMS.

Out and About

Review Section staff gave a presentation at Casey Family Programs in March, at the invitation of WSIRB member Dr. Alan Puckett. The presentation focused on the authority of IRBs, WSIRB jurisdiction, and review of social and behavioral research. Review Section staff welcome requests for briefings, in-services and orientations from all interested agencies and institutions.

On the Move

The Review Section moved to a new space within the DSHS Human Services Building (OB-2) in December. With a burgeoning workload and addition of staff, the HRRS was scattered among workstations and had no central meeting space. All staff are now co-located in one section, thus helping to increase communication, centralization of records and workflow efficiency. The new location is designated as 3NW, 3rd Floor, Human Services Building. All contact information is unchanged.

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

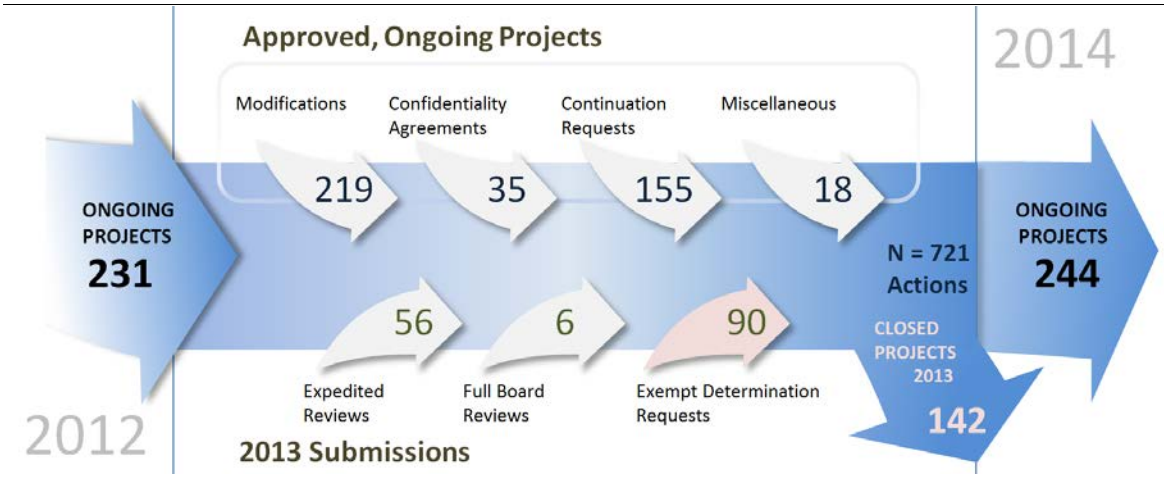
Washington Administrative Code:

- 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 2013



In the illustration above, "Submissions" refers to the number of reviews rather than the number of new projects. This flowchart provides information on the day-to-day workload of the WSIRB for 2013.

CURRENT PROJECTS

Modifications (219)
Modifications refer to study changes, such as adding research staff, new aims or activities, or changes to study materials (e.g., consent forms), samples, or instruments. Modifications may be made at the direction of the WSIRB or initiated by the study team. All modifications require WSIRB approval.

Confidentiality Agreements (35)
Confidentiality Agreements refer to legally-binding agreements between researchers and state agencies, and are required for studies involving use and disclosure of state agency individually identifiable personal records in the absence of individuals' or legally authorized representatives' informed written consent. Agreements may also be otherwise required. These Agreements generally 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 of up to $10,000 for each violation. Agreements are prepared and staffed by the HRRS through applicable state agencies.

Continuation Requests (155)
Continuations refer to WSIRB reviews of ongoing studies, whose periods of WSIRB approval are set to expire. IRB approval may not exceed one year from initial approval: *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 (18)
This includes all other actions submitted to or taken by the WSIRB, and may include reports of adverse events or other unanticipated problems involving risks to subjects or others (UPIRTSOs), deviations to WSIRB-approved procedures, and suspensions or terminations of research.

ONGOING & NEW PROJECTS

Starting 2013 with 231 ongoing projects, the Washington State Institutional Review Board received 62 new projects submitted for review, while 49 projects were closed. Two hundred, forty-four projects were ongoing at the close of 2013.

Expedited Reviews (56)
Review of research by the WSIRB Chair or designated, experienced WSIRB member(s), rather than by the entire WSIRB at a convened meeting. Federal law permits expedited review for certain kinds of research involving no more than minimal risk, and for minor changes in approved research [45 CFR §46.110].

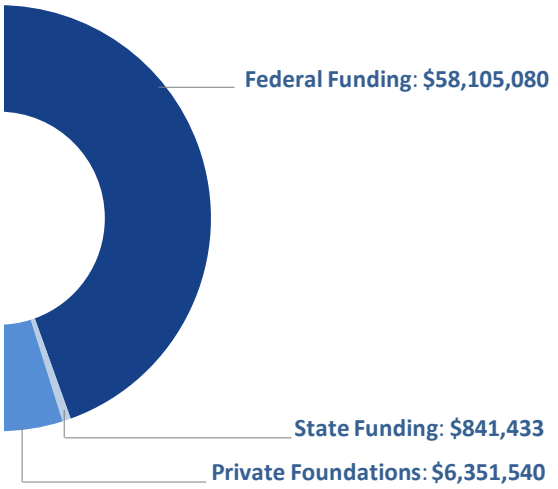
Full Board Review (6)
Review of research at a convened meeting at which a majority of the membership of the WSIRB is present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those WSIRB members present at the meeting.

Exempt Determination Requests (90)
To qualify as exempt from further WSIRB review, research must fall only within one or more of the categories of exempt research at 45 CFR Section 46.101(b)(1)-(6). Any such research that may pose greater than minimal risk or involve vulnerable subjects may be required to undergo expedited or full WSIRB review.

NEW PROJECTS REVIEWED

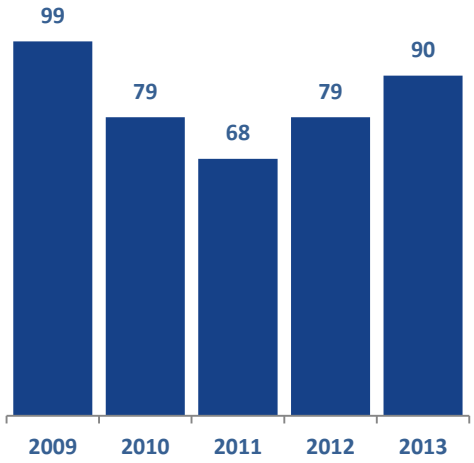
FUNDED PROJECTS TOTAL $65,298,053

New Proposals Reviewed (Expedited and Full board): 44



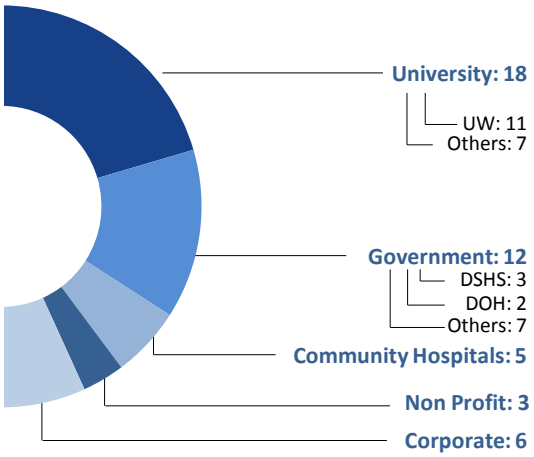
The chart above indicates **the sources of funding for new studies reviewed** during 2013. Among the 44 studies reviewed, 30 (sixty-eight percent) reported that they were funded, but not all disclosed funding amounts. The U.S. Department of Health and Human Services was the largest sponsor of reviewed research.

EXEMPT DETERMINATION REQUESTS (90)



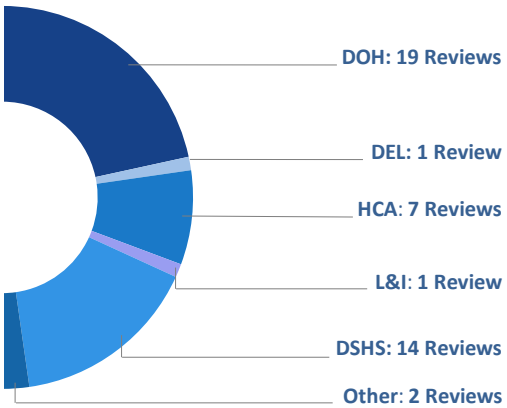
During 2013, forty-eight percent of Exempt Determination Requests (EDRs) were determined to be research that was exempt, while forty-nine percent were determined *not* to qualify as research involving human subjects. Two EDRs were determined to be research that was *not* exempt from human subjects regulations.

RESEARCHER AFFILIATION (44)



Nearly forty-one percent of principal investigators were university-based, with the University of Washington accounting for twenty-five percent and all other universities accounting for the other sixteen percent of reviews. Researchers affiliated with Government accounted for twenty-seven percent of all reviews, Corporate fourteen percent, Community Hospitals eleven percent, and Nonprofit entities six percent.

STATE AGENCY (44)



Forty-three percent of all applications submitted for review in 2013 were in the jurisdiction of DOH, while DSHS accounted for thirty-two percent of applications, HCA accounted for sixteen percent, and L&I and DEL each accounted for two percent of applications.
Note: applications and EDRs were only counted once, even if they were resubmitted during the same calendar year.

ONGOING TRAINING OF WSIRB MEMBERS

Continuing training and in-service for WSIRB members and HRSS staff is considered essential to maintaining knowledge in the furtherance of human subject protections. Training and in-service may focus upon current issues relating to human subjects protections and the review of research (e.g., Internet-based research, agency records as "human subjects"), innovative research for which risks to subjects or benefits are unknown or poorly understood, and changing regulations or their interpretation by regulatory agencies (e.g., multi-study site IRB review; genetic research). WSIRB members and HRRS staff are actively involved as facilitators of discussions of the scholarly and professional literature that raise these and other issues. Additionally, HRRS staff and WSIRB members are encouraged to attend workshops (including webinars) sponsored by OHRP and professional organizations in the field. Listed below are just a few of the many training topics addressed by the WSIRB in 2013.

Perlman, D. (Winter 2012). **Rethinking Local Institutional Review Board (IRB) Review at State Health Departments: Implications for a Consolidated, Independent Public Health IRB.** Journal of Law, Medicine & Ethics, 40(4), 997-1007.
Moderators: *Lauren Jenks, M Patricia deHart, Jovi Swanson*
The author presents problems that may arise when local health department IRBs review research, including for example the inadequacy of infrastructure, staff and resources to support an internal IRB; the potential for interference with and pressure upon IRBs by political appointees or managers; pressures on staff involved with human subjects reviews; and the challenges in determining whether an activity is public health practice or research for purposes of IRB review. The author proposes two models for local health departments: use of a central IRB serving multiple public health entities, and establishing a local IRB within a single agency. WSIRB members discussed many of the assumptions in the article, particularly that local review may not be adequate, or that an all-volunteer IRB may not have sufficient expertise or interest. Particular attention was focused on the cost-benefit model proposed by the author, which may fail to sufficiently acknowledge the ethical underpinnings of the IRB's responsibilities and the primacy of human subjects protections.

Mudaly, N., and Goddard, C. (2012). **Letter to the Editor: The Urgent Need for Ethical Guidelines to Protect Children in the Dissemination of Research Findings**. Child Abuse & Neglect, 36 (11-12), 798-799.
Moderator: *Alan Puckett*
This article focused on the ethical dimension of using photos of abused children in public forums, such as conferences and poster sessions. WSIRB members discussed similar situations that may raise concerns about consent of subjects, retention of visual materials such as photos and videos, and potential harms that could occur as a result. The WSIRB also discussed procedures that were implemented regarding use of visual media in research projects reviewed and approved by the WSIRB.

July 2013 OHRP Quality Assessment Workshop - Focus on Consent Forms
Moderators: *Lilly Moneer, Katrina Wynkoop Simmons, and Maggie Frederick*
OHRP offered a free one-day workshop in Portland, Oregon on July 18, 2013. The workshop focused primarily on informed consent issues. The morning session covered the federal human subjects regulations and their applicability, particularly the regulations regarding informed consent and waivers of consent. The afternoon session featured Elizabeth Buchanan, Ph.D., University of Wisconsin-Stout, who provided an assessment of Internet-based and social media research. Graphic representations of the interplay of social media and collection of personal information were depicted, as well as videos of online recruitment tools.

Using Review Worksheets, Part 2: Study Population
Presenter: *T. Howard Stone*
Investigators are expected to provide a thorough description of their intended study population so the WSIRB may determine: (1) appropriate inclusion and exclusion of individuals as human subjects and (2) whether any additional protections may be needed for individuals who are considered vulnerable as human subjects. Selection of subjects must be equitable: the WSIRB must consider whether those who share the burdens of research would also benefit from it. Consideration should be given as to whether study subjects are appropriate, given the research design and procedures. Consideration should also be given to whether all potential vulnerabilities have been identified. Further, federal regulations require the WSIRB to make specific determinations whenever a study may involve vulnerable subjects, such as for example, pregnant women, prisoners, or children. Materials required for submission for the WSIRB's consideration are intended to collect the information necessary for WSIRB members to determine whether these requirements have been met.

ASK THE WASHINGTON STATE INSTITUTIONAL REVIEW BOARD

Q: I have approval from my own institution's IRB. Do I need to submit my study for review by the WSIRB?

A: You might. If a study involves disclosure of Washington State agency records, such as the cancer registry, Medicaid claims, birth records, or other records held by DSHS, DOH, DEL, HCA or L&I, WSIRB review would be required. If you plan to contact agency clients or beneficiaries with the assistance of the state agency, the study requires WSIRB review. The WSIRB may only need to review the component(s) in its jurisdiction, rather than the entire study. Always call the DSHS Human Research Review Section before submission to discuss the details of your project.

Q: Is there a charge or fee for WSIRB review?

A: Perhaps. The WSIRB is developing plans to require payment of fees for its review of extramurally funded research. Payment will be required in advance of review, and whether or not the study is undertaken. Investigators affiliated with the Washington State agencies that provide support to the WSIRB and HRRS would not be charged. When finalized, a fee schedule will be posted on our website.

Q: What kind of documentation of human subject protections training is required by the WSIRB?

A: The WSIRB accepts documentation of training through the Collaborative Institutional Training Initiative (CITI), the National Institutes of Health (NIH), as well as training provided by the investigator's home institution. Regardless of provider, training content must conform to WSIRB requirements. Investigators should consult our website for updates.

Q: The WSIRB application form includes Appendix G and Appendix H—what are they for, and how are they different?

A: Appendix G focuses on requests for identifiable records; availability of requested records and the time, effort and expertise required to pull or extract the requested records are addressed in this Appendix G. **Appendix H** focuses on all *other* resources requested from the state agency, such as mailing advance letters to eligible clients; setting up toll-free lines for clients to opt out of study participation; processing returned postcards; and use of state agency facilities or offices to recruit and interview subjects.

Q: What happens if I don't respond to reminders about submitting a Continuation Approval Request (CAR) or other WSIRB requirements?

A: Failure to respond to WSIRB requirements in a timely manner has consequences. Reminders are a courtesy only and may not always be sent out; investigators are responsible for appropriate planning of their Continuation Approval Requests (CARs) and other study related actions. Failure to timely submit CAR materials may result in suspension or termination of studies for noncompliance, about which researchers' home institution IRB, OHRP, funding agency or sponsor and others will be informed. Termination of studies for which the study team received identifiable state agency records under a Confidentiality Agreement will be reported to the Attorney General, which office may pursue criminal misdemeanor as well as civil penalties of up to $10,000 per violation. If investigators do not respond in a timely manner to reviews of their studies, the studies will be canceled.

Q: My study involves only use of state agency identifiable records—do I still need to describe the risks and benefits?

A: Yes. This section of the WSIRB application must be completed for ALL research. It is not acceptable to state, without further explanation, that a study poses "no" or "minimal" risk to subjects. Any use of identifiable or coded records poses some risk. One of the most common reasons for delays in WSIRB review of research is due to the investigator's failure to adequately describe the potential risks, including their probability and magnitude, and plans to mitigate these risks.

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

A: An exemption cannot be granted if you have already begun the activity. All requests must be submitted before beginning the work. Exemptions cannot be granted retroactively by an IRB; journals requiring IRB review may not accept your article for publication. Plan accordingly.

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, call WSIRB staff to discuss your plans. Staff may advise you to submit an Exempt Determination Request. You will receive a written response that informs you if the activity is not considered research involving human subjects, or if it is research that is exempt from further WSIRB review.

SPOTLIGHT ON SELECTED STUDIES

The following section spotlights, by agency, proposals that were either reviewed or closed during 2013. 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.

Department of Social and Health Services (DSHS)

"Camp Inside Out"

Principal Investigator: Kym Ahrens, M.D., M.P.H., Seattle Children's Research Institute.

The researcher has developed a program intended to reduce risk of sexually transmitted infections that is tailored specifically to youth in foster care. The intervention program consists of 4-day intensive, overnight camp, in which skills and activities-based content are delivered to small groups of foster youth. Topics covered in the intervention will include: basic STI/HIV and pregnancy-related knowledge and skills, STI/HIV and pregnancy-protective self-efficacy, choosing good partners, peers, and mentors, content to enhance global self-esteem, interpersonal effectiveness/assertiveness, planning and goal setting, and healthy emotion regulation skills. The researcher will pilot-test the intervention over two summers and plans to collect baseline, post-intervention, and 6 month follow-up data to determine changes in knowledge, attitudes, and behaviors related to STI and pregnancy risk. As foster youth have 3-14 times the risk of several STIs and 2-4 times the risk of early pregnancy compared with youth in the general population, interventions to address interpersonal skill deficits may help to decrease these risks.

"Estimating the Costs of Child Abuse and Neglect"

Principal Investigator: Marna Miller, Ph.D., Washington State Institute for Public Policy.

The Washington State Institute for Public Policy created a benefit-cost model to estimate the monetary value, both to the State and individuals, of interventions that reduce the occurrence of child abuse and neglect, as well as the monetary value of changes in out-of-home placement in the child welfare system. The researchers, as directed by the Legislature, will develop and periodically update an inventory of cost-effective prevention and intervention services. In order to improve the estimate of tax-payer costs, the researchers will use child welfare records linked to child dependency cases in the Superior Court, to: 1) identify families and children reported to child protective services; 2) estimate the lifetime prevalence of child abuse and neglect (i.e. the likelihood that a child will be the alleged victim before his or her 18th birthday); 3) estimate the cost of services provided to families; and to 4) estimate court costs associated with dependency cases.

"Dementia Day Services Evaluation"

Principal Investigator: Rebecca Logsdon, Ph.D., University of Washington School of Nursing.

The primary objective of this study was to evaluate a new program of Dementia Day Services developed by the DSHS Aging and Disability Services Administration as a component of the Alzheimer's Disease Demonstration Grant to States Program. Dementia Day Services were provided within existing Adult Day Centers or Day Health Centers and provided specialized dementia services not typically available. The objectives of this investigation were to evaluate whether Dementia Day Services improved quality of life, mood, behavior, or functional status for participants with dementia and whether caregivers of these participants experienced decreased stress, burden, anger or depression, compared with dyads receiving usual community services.

After 6 months, individuals with dementia who attended a Dementia Day Services program exhibited significantly fewer depressive behaviors and a trend toward fewer total behavior problems than those in the comparison group. No significant differences were found in health or quality of life between the treatment and comparison group. Caregivers whose care recipient attended a Dementia Day Services program exhibited significantly less distress over participant behavior problems and a trend toward less distress over disruptive problems than caregivers in the comparison group. No significant differences were found in caregiver mood, perceived stress or burden between the treatment and comparison group. No differences were found in residential care placement between the treatment and comparison group.

SPOTLIGHT ON SELECTED STUDIES (CONTINUED)

Department of Health (DOH)

"Elective Induction of Labor and Pregnancy Outcomes"

Principal Investigator: Sascha Dublin, M.D., Ph.D., Group Health Research Institute.

Each year in the US, up to 490,000 pregnant women undergo elective induction, an intervention to bring on labor without a medical reason. Whether this causes risks to the woman or fetus is unclear. This multiphase retrospective study will use health plan electronic medical records and birth records to evaluate induction of labor and birth outcomes for births occurring between 2001 and 2013. The researchers will conduct 8,000 brief medical record reviews to determine true exposure status (elective induction vs. expectant management) and an additional 3,500 medical record reviews to evaluate true outcome status and risk factors for adverse pregnancy outcomes.

"Addressing Psychosocial Disparities in Rural Hispanic Cancer Survivors"

Principal Investigator: Rachel Ceballos, Ph.D., Fred Hutchinson Cancer Research Center.

The Institute of Medicine and National Research Council have identified the psychosocial needs of cancer survivors as a clinical priority. For many survivors, distress from long-term medical, financial, and socio-emotional burdens of survivorship can persist well beyond completion of primary treatment for cancer. Among Hispanics, the burdens of survivorship are coupled with language and socio-cultural barriers that contribute to disparities in resource availability and uptake. As a result, Hispanic cancer survivors experience higher levels of distress and significantly lower quality of life compared to their non-Hispanic White counterparts. In this study, a Spanish-language support program based in Social-Cognitive Theory will be developed for rural Hispanic survivors of female reproductive cancer and evaluated using psychosocial and biological outcomes. Female reproductive cancers were selected as this study's focus because breast cancer is the most frequently diagnosed cancer while cervical, uterine, and ovarian cancer remain among the leading cancers diagnosed in Hispanics.

Department of Labor and Industries (L & I)

"Hospitalization for Work-Related Injury"

Principal Investigator: Sara Wuellner, M.P.H., Washington State Department of Labor and Industries.

This research will estimate the rate of work-related hospitalizations in Washington as part of the Governor's "Results Washington" initiative. They will also evaluate compliance with the regulation that employers report injured worker hospitalizations to the L&I Division of Occupational Safety and Health (DOSH). CHARS records will be linked to workers compensation claims. Linked records will be compared to hospitalizations reported to DOSH by the injured worker's employer. By linking these data sets, the researchers hope to develop an industry-adjusted inpatient hospitalization rate and thereby improve the employer-reported work-injury hospitalization notification system to allocate DOSH prevention resources appropriately.

"The Evaluation of the Physical Load of Four Lateral Patient Transfers"

Principal Investigator: Stephen Bao, Ph.D., Washington State Department of Labor and Industries.

Every year, health care providers, such as nurses and nursing aides, suffer serious, debilitating and potentially career-ending musculoskeletal disorders and injuries. The most recognized cause of these injuries is the lifting, repositioning and handling of patients. This study investigated the differences between four bed-to-wheelchair lateral transfer methods. Two health care providers transferred two different sized "patients" who were partially weight bearing. Electromyography (EMG) was used to capture the bilateral muscle activities of the workers of the biceps, upper trapezius, infraspinatus, extensor digitorum and erector spinae. Video recordings were taken to perform time studies on workers' movements. Overall muscle activity among each transfer technique for each muscle group significantly differed. This study demonstrates that this type of analysis can be used to obtain useful information for targeted injury prevention efforts. While the focus of previous research has been primarily on this single task as the greatest contributor of injury, other tasks involved in a transfer may pose as great or greater risk of injury.

SPOTLIGHT ON SELECTED STUDIES (CONTINUED)

Health Care Authority (HCA)

"Efficacy of Prescription Monitoring Program Use in Emergency Departments"

Principal Investigator: Benjamin Sun, M.D., M.P.P., Oregon Health and Science University.

The U.S. Congress, the National Institute of Drug Abuse, and the Centers for Disease Control and Prevention have identified prescription drug abuse as a top public health problem. The Washington State Legislature mandated that all emergency department providers register for the state Prescription Monitoring Program (PMP) in April 2012. This research focuses on a critical policy question: Does PMP use in the emergency departments reduce hospital visits, costs, and deaths related to prescription drugs? Using Medicaid claims and eligibility records, the researchers are evaluating predictors of PMP use by emergency department providers; the impact of emergency department PMP use on total, inappropriate, and appropriate opioid prescribing; the impact of emergency department PMP use on patient outcomes; and will also compare PMP efficacy in emergency department with non- emergency department ambulatory care settings.

"Improving Care for Children with Complex Needs – Medicaid Expenditure Study"

Principal Investigator: Rita Mangione-Smith, M.D., M.P.H., Seattle Children's Research Institute.

Children with complex medical needs require higher than usual health care services when compared to other children. These children are often difficult for their primary care providers to care for, due to their multifaceted conditions. As a result, the children often end up in the emergency department or are admitted to the hospital. Seattle Children's Hospital launched the Comprehensive Case Management Service (CCMS) in 2010 and began a randomized controlled trial that provides standardized services that support the child's family and primary care provider. The researchers are using Medicaid claims data for both intervention and control group subjects pre- and post-implementation of the CCMS, in order to assess whether CCMS reduces the cost of care while increasing the quality of care for these children.

Department of Early Learning (DEL)

"Mother and Infant Home Visiting Program Evaluation (MIHOPE)"

Principal Investigator: Charles Michalopoulos, Ph.D., M.D.R.C..

Home visiting programs attempt to intervene at home with parents to support and improve their socialization, health, and education practices, with the goal of improving early childhood health and development. The study is required by the federal Patient Protection and Affordable Care Act of 2010. The study's primary objectives are to estimate the effects of home visiting programs across a set of domains of maternal and child well-being specified in the authorizing legislation; to investigate how those effects vary for different home visiting approaches and across subgroups of families; to describe how local home visiting programs are implemented and what features of the local, state, and national environments affect that implementation, and to explore how variation in the program design and implementation of local home visiting programs influence impacts. The researchers are requesting birth records, child welfare records (FamLink) and Medicaid claims records to evaluate program effects.

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.

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 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.

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

Protecting the Rights of Human Research Subjects

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

Washington State Department of Social & Health Services

Washington State Department of Health

Washington State Department of Early Learning

Washington State Health Care Authority

Washington State Department of Labor & Industries