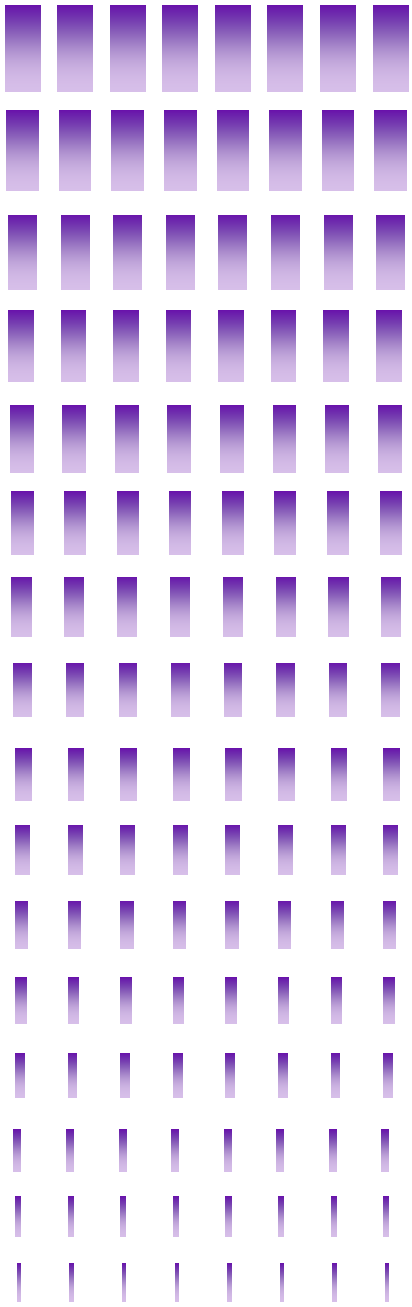

Activity Report
Washington State Institutional Review Board
Fiscal Year 2005

August 2005

Washington State Department of Social and Health Services
Management Services Administration
Research and Data Analysis Division
Human Research Review Section

ACTIVITY REPORT

DEPARTMENT OF SOCIAL AND HEALTH SERVICES
DEPARTMENT OF HEALTH
DEPARTMENT OF LABOR & INDUSTRIES

WASHINGTON STATE INSTITUTIONAL REVIEW BOARD

Fiscal Year 2005

May 2006

Department of Social and Health Services
Management Services Administration
Research and Data Analysis
Human Research Review Section
Olympia, Washington 98504-5205

When ordering please refer to
Report # 11.127

DEPARTMENT OF SOCIAL AND HEALTH SERVICES

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Liz Dunbar, Deputy Secretary

MANAGEMENT SERVICES

Kathleen Brockman, Chief Administrative Officer

RESEARCH AND DATA ANALYSIS DIVISION

Elizabeth Kohlenberg, Ph.D., Director

HUMAN RESEARCH REVIEW SECTION

Michael A. Garrick, Ph.D., Coordinator

ACKNOWLEDGEMENTS

This report is dedicated to the past and present members of the Washington State Institutional Review Board, who have contributed their time and expertise to represent the interests of those who have been asked to participate as subjects in research conducted within the jurisdiction of the Department of Social and Health Services, the Department of Health, and the Department of Labor and Industries.

Updated August 2005

WASHINGTON STATE INSTITUTIONAL REVIEW BOARD A

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Coordinator
DSHS Human Research Review Section

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Senior Research Associate
Washington Institute, Western Branch

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

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Prisoner Representative

Nancy Anderson, M.D., M.P.H.
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DSHS Medical Assistance Administration

David Bonauto, M.D., M.P.H.
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Manager, Research and Data Analysis
DOH Emergency Medical and Trauma Prevention

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President & Executive Director
Disability Fund

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DOH Environmental Health Programs

Updated August 2005

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DOH Newborn Screening Program

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Eastern Washington University

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Lead Psychologist
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Western State Hospital

Ronald Williams, M.D., M.P.H.
Medical Director
DSHS Juvenile Rehabilitation Administration

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EXECUTIVE SUMMARY

THIS REPORT PROVIDES AN OVERVIEW OF THE WASHINGTON STATE INSTITUTIONAL REVIEW BOARD. IT SUMMARIZES THE BOARD'S AUTHORITY AND FUNCTIONS, OUTLINES THE HUMAN RESEARCH REVIEW PROCESS, AND DESCRIBES MAJOR ACTIVITIES DURING FISCAL YEAR 2004. IT ALSO INCLUDES A LOG OF ALL RESEARCH PROJECTS WHICH WERE REVIEWED DURING THIS PERIOD.

Under Federalwide Assurances with the Department of Health and Human Services, the Washington State Institutional Review Board reviews and approves research (except exempted categories) sponsored by the Department of Social and Health Services (DSHS), the Department of Health (DOH), or the Department of Labor and Industries (L&I), conducted by or under the direction of any employee of agent of these state agencies, using any DSHS, DOH, or L&I property or facility, or using any non-public information held by these state agencies to identify or contact human research subjects or prospective subjects.

The review process is intended to protect the rights and welfare of subjects participating in the research, and to assure that the research is sound and is likely to produce benefits which are greater than the risks to subjects. The review also protects the departments from liability resulting from improperly conducted research.

The Washington State Institutional Review Board is comprised of professionals working both within and outside these three state agencies. Each Board has scientist members, and members whose primary interests are in non-scientific areas. Board members volunteer a substantial amount of their time to review proposals submitted by researchers. The membership of Review Board A and Review Board B is shown on pages v and vii.

The Review Board receives administrative support from the Human Research Review Section in the Department of Social and Health Services. Staff in the Section also serve as the Executive Secretary and Associate Executive Secretary of the Board.

More information about the departments' human research review policies and procedures, and copies of the *Washington State Agency Policy on Protection of Human Research Subjects* (revised April 14, 2003), the *Washington State Institutional Review Board Procedures Manual* (April 2004), and the departments' Research Application forms, are available on the Review Section's website: http://www1.dshs.wa.gov/rda/hrrs/. You may contact the Review Section at (360) 902-8075 or by email at: wsirb@dshs.wa.gov.

ACTIVITY REPORT

Department of Social and Health Services
Department of Health
Department of Labor and Industries

Washington State Institutional Review Board

Fiscal Year 2005

I. PURPOSE

The Department of Social and Health Services (DSHS), Department of Health (DOH), and Department of Labor and Industries (L&I) are responsible for protecting the rights and welfare of clients, employees, and members of the general public who serve as subjects in research within the departments' jurisdiction. DSHS/DOH/L&I have fulfilled this responsibility by establishing a formal policy for the protection of human subjects, and by supporting a standing Institutional Review Board (IRB) which operates under the auspices of Federalwide Assurances (FWAs) with the federal Department of Health and Human Services. The Washington State Institutional Review Board (WSIRB) housed in the Department of Social and Health Services is the IRB for the three state agencies.

The WSIRB conducts an ethical and a technical review of proposed research to assure that the rights and welfare of subjects are adequately protected, and that risks are minimized, are not unreasonable, and are outweighed by potential benefits. The review also assesses whether the proposed design and methods are adequate and appropriate in light of stated project objectives.

II. AUTHORITY

The departments' human subjects protection policy complies with federal regulations (45 CFR 46, 45 CFR 164) and with protective requirements of state law (e.g., RCW 42.48; RCW 70.02). Washington Administrative Code (WAC 388-10), DSHS Administrative Policy 12.01, DOH Administrative Policy 03.001, and L&I Administrative Policy 9.43, prohibit any departmental service or administrative unit from allowing the conduct of research and related activities until the plans or protocols have been approved by the Review Board. The departments' policy is described more fully in the *Washington State Agency Policy on Protection of Human Research Subjects*, revised April 14, 2003, available to download from the Review Section website: http://www1.dshs.wa.gov/rda/hrrs/.

III. ACTIVITIES SUBJECT TO BOARD REVIEW

Except for research activities specifically exempted in the *Washington State Agency Policy on Protection of Human Research Subjects,* Section XI, the departments' human research review policy applies to all research and related activities that are (i) sponsored by DSHS/DOH/L&I, (ii) conducted by an employee or agent of DSHS/DOH/L&I, (iii) which use any DSHS/DOH/L&I property or facility, or (iv) which involve the use of DSHS/DOH/L&I non-public information to identify or contact human research subjects or prospective subjects. The policy applies to research and related activities contracted by DSHS/DOH/L&I to non-departmental organizations or individuals, regardless of whether the research involves department clients or a nondepartmental subject population.

A definition of research and a list of categories of research that are exempt from review are provided in the *Washington State Agency Policy on Protection of Human Research Subjects,* Sections IV and XI, respectively. In addition, Guidelines developed by the Centers for Disease Control and Prevention, on the Review Section's website: http://www1.dshs.wa.gov/rda/hrrs/, are helpful in distinguishing between public health research and public health practice. However, these documents may not always provide enough information to distinguish between research and related activities that are subject to review and administrative data collection or program monitoring activities that are not subject to review. If in doubt, researchers and program managers should contact Review Section staff to determine the boundaries of Review Board jurisdiction.

IV. ADMINISTRATION

The DSHS Human Research Review Section is a three-person administrative unit that provides staff support to the Review Board, and coordinates and administers the human research review policy. The Section Coordinator and Review Coordinator provide liaison between DSHS/DOH/L&I and other agencies and institutions on human subjects protection issues. The Section Coordinator serves as the Executive Secretary of the Review Board, the Review Coordinator as the Associate Executive Secretary.

Research proposals requiring Board review must be submitted on the departments' application forms. Research application forms may be downloaded from the Review Section's website. Review Section staff are available to assist researchers in completing their applications, and to consult on jurisdictional and policy or procedural questions. Department researchers and managers who are unsure of whether a proposed activity requires Board review should consult with Review Section staff.

V. REVIEW BOARD FUNCTIONS

The primary function of the Washington State Institutional Review Board is to protect the interests of individuals participating in research within the departments' jurisdiction. The Review Board performs this function by reviewing proposed research plans, and, if necessary, by assisting researchers in revising their plans to conform to accepted ethical standards and regulatory requirements. An important secondary function of the Review

Board is to provide DSHS/DOH/L&I management with the necessary expertise to determine whether proposed research is valid, worthwhile, and in compliance with federal and state statutes and regulations. DSHS/DOH/L&I administrators, managers, and supervisors are encouraged to refer all inquiries regarding human subjects research to the Review Section.

VI. REVIEW BOARD MEMBERSHIP

Review Board members are chosen to represent the diversity of programs administered by DSHS/DOH/L&I, and to provide the necessary expertise to conduct a thorough ethical and technical review of proposed research. The Review Board is comprised of Board A, a general purpose board, and Board B, which specializes in the review of mental health, juvenile justice, and alcohol and substance abuse research, but which reviews other research as well.

Each Review Board includes at least two physician members who are licensed to prescribe drugs in Washington State and at least one member whose primary interests are in nonscientific areas. The majority of Board members have graduate-level training in statistics, research design and methods, and many are employed in scientific research positions. Each Board retains at least one member whose primary interest is in advocating for the rights of department clients, patients, or wards. Although the majority of members are department employees, the Board also includes university faculty and representatives of the general community who are unencumbered by possible departmental interests. The current membership of Review Board A and Review Board B is listed on pages v and vii.

VII. REVIEW PROCESS

Investigators wishing to conduct human subjects research which falls under DSHS/DOH/L&I jurisdiction should submit their application to the Review Section. Depending on the nature, scope, and complexity of the proposed research, applications are either referred to one of the Review Boards for consideration at a regularly scheduled meeting, or are reviewed by two or more Board members through the expedited process (See *Washington State Agency Policy on the Protection of Human Research Subjects*, Section X for activities that are eligible for expedited review).

Proposals that require full Board review are pre-reviewed before they are placed on the agenda of a Board meeting. An electronic copy of a proposal for full Board review must be submitted no later than the application deadline for the meeting. Researchers will be informed of the results of the pre-review no later than one week after the application deadline. Researchers then have one week to either revise their application or submit supplemental information as an addendum to their application before the proposal is sent to Board members prior to the meeting. One member is asked to be the “primary reviewer” and to present the proposal to the Board at the meeting. Researchers are asked to be available by telephone to provide factual information and to clarify issues during review of their proposal at the Board meeting. Occasionally, the researcher is invited to attend the meeting to respond to questions or concerns or to provide supplementary information.

Prior to discussion of specific research proposals, the Chair asks Review Board members to disclose any potential conflicts of interest they may have with items on the meeting agenda. Conflicts of interest may arise for either financial or personal reasons. Review Board members who have a conflicting interest with proposals on the agenda do not participate in the Board's review, except to provide information requested by the Review Board.

Members who have a significant conflict of interest recuse themselves from consideration of the research proposal and leave the meeting room during discussion and voting. They are not counted in the quorum for consideration of that agenda item. Members who have a less significant conflict of interest may remain in the room during consideration of the proposal, but do not participate in the discussion except to answer questions, and abstain from the vote. Members who abstain from voting are counted in the quorum for consideration of that item.

The criteria for approval of research are listed in the *Washington State Agency Policy on the Protection of Human Research Subjects*, Section VII. The Board also uses the WSIRB Review Worksheet and the Review Presentation Guide, published by the Review Section and posted on the Review Section's website, as checklists to promote thorough and consistent reviews of all research proposals.

Following presentation of the proposal, the primary reviewer is asked for a disposition recommendation. When the motion has been made and seconded, other members are invited to share their comments and/or concerns about the proposal with the Board. The disposition motion may be amended or withdrawn on the basis of the additional discussion. Final disposition of the proposal is decided by a simple majority vote of all members present at the meeting. The Board may approve the proposal as submitted, approve the proposal subject to specified conditions, defer consideration of the proposal pending submission of supplemental information, or disapprove the proposal.

Unfavorable review dispositions (i.e., disapproval, restrictions, special approval conditions) are binding and not subject to administrative override. Researchers may appeal unfavorable review dispositions directly to the Review Board. Each proposal approved by the Board is subject to administrative review and concurrence by the appropriate DSHS/DOH/L&I division director or assistant secretary.

If approved research is to be conducted within departmental offices, institutions, or other facilities, the Review Section will provide local administrators with information on Board approved procedures, with a request that they supervise the research to ensure that these procedures are followed.

The *Washington State Institutional Review Board Procedures Manual* (April 2004) provides additional details regarding the review process, management and support of the Review Board, and Review Board operations. The *Manual* is available on the Review Section's website at http://www1.dshs.wa.gov/rda/hrrs/.

VIII. MAJOR ACTIVITIES: FISCAL YEAR 2005

Human Subject Protection Activities at the National Level

In February 2005 the federal government settled its case against the University of Pennsylvania and the Children's National Medical Center. The Justice Department sued these institutions for civil fraud in the case of a Jesse Gelsinger, who died as a result of his participation in a gene transfer trial in 1999. In addition to fines of over $500,000 for each institution, the researchers were restricted in their conduct of research and receipt of federal research funds. The Principal Investigator was barred from conducting FDA-sponsored research for five years, and, among other restrictions, was required to have a medical monitor oversee all his clinical activities for three years.

Congress

The movement to increase access to both positive and negative results of drug trials gained ground, as did the push for a national registry of drug trials. This development follows a lawsuit against GlaxoSmithKline which alleged that the pharmaceutical company had hidden the increased risk of suicide among children taking Paxil. GSK performed five trials of the drug in children. The results of only one of these studies were made available to health care providers; the results were ambiguous. As a result of the lawsuit, GSK was the first pharmaceutical company to voluntarily create a registry of clinical trials. In a similar move, the American Medical Association requested that HHS implement a national registry of all clinical trials currently under way. The AMA plan would require all research involving human subjects to be listed in the registry in order to obtain IRB approval. In a later development, Rep. Edward Markey presented a bill to Congress that would revise the Public Health Service Act to require registration of clinical trials as a condition of federal funding. A companion bill was also introduced into the Senate.

The "Pharmaceutical Research and Manufacturers Accountability Act of 2005" was introduced in Congress by representatives Stark, (D-California) and Berry (D-Arkansas). The bill, introduced in February 2005, carries severe penalties for failing to disclose evidence of serious adverse drug events: a minimum sentence of 20 years to life in prison and millions of dollars in fines. Pharmaceutical company executives would also face stiff fines if they failed to submit an annual report of all serious adverse events to the FDA.

Senator Dodd (D-Connecticut) introduced a bill to require registration of all clinical trials--including trials of experimental devices. If passed, the requirement for registration would apply to all clinical research, regardless of funding source. The bill would strengthen public access to clinical trial data, both positive and negative. Rather than create a new registry, the bill would expand the registry operated by the National Library of Medicine.

Office of Human Research Protections

Two new Subparts to the federal human subjects protection regulations, 45 CFR 46, were implemented in FY 05. Subpart F contains requirements for registration of IRBs that review research supported by the Department of Health and Human Services or research which falls within the jurisdiction of FDA regulations. There is now a single registration

system for both agencies, although FDA requirements differ slightly from HHS requirements. Subpart E requires that all FWA-institutions ensure that agency officials, IRB staff, IRB members, and investigators receive initial and continuing education in the requirements for human subjects protection. The WSIRB has required such training since July 2002.

A federally sponsored research protocol was referred by the National Institutes of Mental Health IRB to OHRP for a "407 Review". An IRB may request a 407 Review when it finds that a protocol involving children is "not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem" (45 CFR 46.407). In such cases, the Secretary of HHS convenes a panel to review the protocol and seeks public comment, usually by publication of the protocol and request for comment in the *Federal Register*. The protocol in question proposed to administer a single dose of dextroamphetamine to children aged 9-18 years to evaluate brain activity by magnetic resonance. As the study involved healthy controls in addition to children with ADHD, the NIMH IRB could not come to agreement regarding the level of risk to child subjects, particularly to control subjects. The protocol was referred to a subcommittee of the FDA Pediatric Advisory Committee, which determined that the research was approvable provided specific design issues were addressed and modifications were made to the research protocol and to the process and documentation of parental permission and child assent. After the Pediatric Ethics Advisory Committee proposed two additional modifications and the FDA's Office of Pediatric Therapeutics endorsed approval, the Acting Commissioner granted approval to the protocol in December 2004.

In September 2004 OHRP published "decision trees" for determining requirements for human subjects review. The first in the series leads through the process of determining whether an activity is research; subsequent charts lead through decisions as to whether human subjects are involved, whether the activity meets federal criteria for exemption, and whether the research comprises minimal risk research which qualifies for expedited review. The decision trees are available on the OHRP website at http://www.hhs.gov/ohrp/.

OHRP is funding an Institute of Medicine study of participation of prisoners in research. The IOM committee, which held its first meeting in March 2005, will consider the ethical bases for research with prisoners as opposed to non-prisoners; develop an ethical framework for conducting research on prisoners; and identify appropriate safeguards to ensure that such research is ethically conducted. The committee will evaluate whether the 1976 findings of the National Commission for Protection of Human Subjects in Biomedical and Behavioral Research are still relevant to research conducted today, in a changed criminal justice and research environment.

National Institutes of Health

Financial conflict of interest, particularly at the National Institutes of Health, remains a focus of human subjects protection at the national level. In May 2005, an NIH panel submitted a list of recommendations to Director Elias Zerhouni. Zerhouni, in testimony before the House Committee on Energy and Commerce, stated that he would work to enhance public trust, increase transparency of internal NIH decisions and procedures regarding conflict of interest, and implement ongoing monitoring of financial arrangements

between NIH researchers and other entities. New financial conflict of interest guidelines may call for additional disclosures than are currently required. The guidelines also reinforce the prohibition on researchers interacting directly with human subjects if they may financially profit from the research results or inventions, and would prohibit senior management from receiving consulting fees or other financial perquisites from research and/or funding decisions which they oversee as part of their official NIH duties.

In September 2004, NIH proposed a new policy for investigators who receive funds from the agency. The NIH would require researchers to submit a final version of manuscripts accepted for publication to the agency, which would then post it on a searchable website. The intent is to ensure the public greater access to research that is publicly-funded, and to ensure more rapid dissemination of research findings to professional groups and other researchers. The new policy was implemented in May 2005; adherence to the policy is not mandatory.

In December 2004, NIH suspended all research on Celebrex and issued a directive to IRBs to conduct clinical safety reviews. This directive follows the cessation of marketing of Vioxx due to increased cardiovascular disease risk, and the potential for other Cox-2 inhibitors to pose similar risks to human subjects of research and patients. The FDA issued related information on the same day, and issued information about the increased risk of CV events when taking Celebrex twice per day. Pfizer ceased direct-to-consumer marketing of Celebrex at the request of the FDA.

In December 2004 the NIH issued new guidelines for research involving coded private information and/or biological specimens. The guidance was revised to ensure consistency with OHRP guidance on this issue. Information investigators must provide has been incorporated into a new version of Form PHS 398. These changes apply to new and competing continuation grant applications and non-competing continuation reports. Additional information is available on the NIH website.

Food and Drug Administration

The FDA issued draft guidance for Investigational New Drug (IND) applications for gene transfer trials, to ensure that human subjects are protected. The guidance appears to be another response to the death of Jesse Gelsinger in a gene transfer trial in 1999. The draft guidance is intended to ensure that such trials meet all the regulatory requirements and provide sufficient information for the FDA and IRBs to evaluate safety and effectiveness of the product.

The FDA also conducted an internal review of conflicts of interest, and issued new measures to manage financial conflict of interest. The FDA will audit outside activities of agency employees on a yearly basis; increase the number and type of employees who must report potential conflicts; and develop a desk manual regarding conflict of interest for agency staff.

An FDA whistleblower, David Graham, M.D., M.P.H., Associate Director for Science and Medicine, asserted in Congressional testimony that the FDA itself failed to protect human research subjects and patients who had taken Vioxx, as evidence of serious adverse events

had been mounting for five years. Dr. Graham cited systemic problems within the FDA as a primary cause of lapse in the national drug safety network.

The FDA held a public hearing in March 2005 to evaluate adverse event reports and the role of IRBs. With the exponential increase in clinical trials in recent years, many IRBs are awash in adverse event reports, sometimes without adequate information to assess risks to subjects. As clinical trials branch out to multi-site and international operations, such reports increase in number and complexity. The public hearing focused on the role of IRBs in reviewing reports of adverse events; what kinds of information and information format would be helpful to IRBs; and changes to the reporting system to make it more relevant and timely for IRBs. For example, adverse events are often submitted without an indication of the drug to which a subject was randomized, without a summary of events across study sites, or aggregate statistics which would be helpful in assessing whether the adverse event is occurring more frequently, has increased in severity, or is unexpected. As human subjects must be informed of foreseeable risks to research participation, evaluation of adverse event reports are key to ensuring ongoing informed consent of subjects, and, in some cases, termination of enrollment or of the trial itself.

Human Subject Protection Activities at the Local Level

Several Review Board members attained 10 years of service: Board B Chair Robert Fineman, M.D., PhD., Medical Consultant at the Department of Health; George Yeannakis, J.D., Seattle University School of Law, the Board's prisoner representative; Robert Mootz, D.C., Associate Medical Director for Chiropractic at the Department of Labor and Industries; Anna Leon-Guerrero, Ph.D., Associate Professor of Sociology at Pacific Lutheran University. The Review Board and Review Section staff appreciate their dedication to the human subjects review process and the care they had taken in reviewing proposals over the years.

The Coordinator of the DSHS Human Research Review Section attended the national PRIM&R conference October 28-31, 2004 in San Diego. PRIM&R is Public Responsibility in Medicine and Research, and is the preeminent national organization for researchers, IRB administrators and IRB members. The theme of the conference was on how to facilitate and improve communication between IRBs and researchers, institutions and study sponsors. A keynote address by Joe Palca, Science Correspondent for National Public Radio, was especially enjoyable and entertaining. Breakout sessions on the implications of HIPAA Privacy and Security Rules on research and on distinguishing between research and non-research activities were especially helpful.

In February 2005, the Review Section conducted a customer survey to assess quality improvement activities. The web-based anonymous survey was administered to researchers who had submitted proposals for review during a four-year period (two years before the QI initiative was implemented and two years after implementation). Links to the survey were sent to 198 researchers, of whom 86 responded. Investigators were asked to rate the importance of several domains in their work and to rate how well the particular domain described the WSIRB. Overall, of the 86 respondents, 66 gave positive ratings, 10 were more or less neutral, and 10 were dissatisfied with their experience with the WSIRB.

The survey covered timeliness and thoroughness of review; response to investigator inquiries; elements of human subjects review such as assessment of risks and benefits, knowledge of federal regulations; and communication with and respect for investigators. Three open-ended items asked researchers to comment on how the human subjects application could be improved (35 comments), what the WSIRB does well (49 comments), and what the WSIRB could improve to better meet investigator needs (46 comments). The survey may be repeated in subsequent years, to monitor improvements in client service.

In an effort to reduce costs, streamline operations, and move to electronic reviews, the Review Section began sending all materials reviewed under expedited review authority and the meeting minutes to Board members in PDF format. This is in tandem with procedures implemented the previous year for initial electronic submission of proposals. Proposals requiring full committee review are administratively pre-reviewed, while expedited reviews are forwarded electronically, usually the day of receipt, to Board members for review. Construction of a new database for tracking research proposals began in late spring 2005. The new database in an Access format will replace the aging Lotus Notes, will automate many features for routine reports, and will offer greater adaptability as the Review Section enhances its electronic capabilities for human subjects review.

In local IRB news, the University of Washington phased in an electronic IRB review and approval system. The system was implemented by department, with anticipated phase-in university-wide in late 2005. The University of Washington was in the news due to an OHRP site visit in February. Information about the visit is available on the UW Human Subjects Division website.

The Review Section began revisions to the human subjects application in February 2005. The revised application will be reformatted to check boxes and text fields, which will allow investigators to skip portions of the application which are not relevant to their research protocol. The application will also include appendices for research involving protected classes of subjects (pregnant women, fetuses and neonates, children, and prisoners), and a revised consent form template. The application will be designed to provide a more user-friendly format, particularly those sections which appear to be problematic in the current application.

The Review Coordinator conducted a series of human subjects protection workshops within DSHS Division of Developmental Disabilities residential habilitation centers. The presentations covered the ethical and regulatory framework, WSIRB function, research involving records, research involving contact with department clients, and other WSIRB requirements. Lisa Weber, Research Manager in DDD, presented DDD requirements for conducting research. These presentations took place in all RHC's; DDD management required attendance by all clinical staff, supervisors, and social workers. The Review Coordinator also conducted a workshop at the Eastern Washington University School of Social Work in April 2005.

Review Section staff also performed outreach to universities in Washington, to explore the possibility of streamlining the human subjects review process for investigators. In April 2005, staff met with the Research Compliance Officer at Washington State University and with School of Social Work administrators at Eastern Washington University. Discussion

focused on the feasibility of establishing IRB Authorization Agreements, in which research falling under the dual jurisdiction of the WSIRB and the respective universities would be reviewed by only one IRB, in most cases by the WSIRB. In other outreach, the Review Coordinator approached the University of Washington School of Public Health regarding the possibility of conducting a human subjects protection training for School students and faculty. Further discussion with the Dean of Research will occur in the future.

The Coordinator of the Review Section was a featured speaker at the Northwest Association for Biomedical Research social and behavioral sciences conference in Spokane in June 2OO5. The talk focused on WSIRB policies and research involving DSHS clients.

IX. REVIEW VOLUME AND TRENDS

Figure 1 provides three measures of Review Board activity during the past 21 years. The number of new research proposals submitted for review increased slowly during the period between 1985 and 1990, increased significantly in 1991, and has fluctuated since that time while continuing a general upward trend.

A better measure of Review Board workload is the total number of projects reviewed during the fiscal year, which includes both initial reviews of new proposals, and annual reviews of continuing projects. The total number of projects reviewed has increased 14% during the most recent ten-year period, from 250 in 1996 to 287 in 2005.

Figure 1
Review Volume
Fiscal Years 1985 - 2005

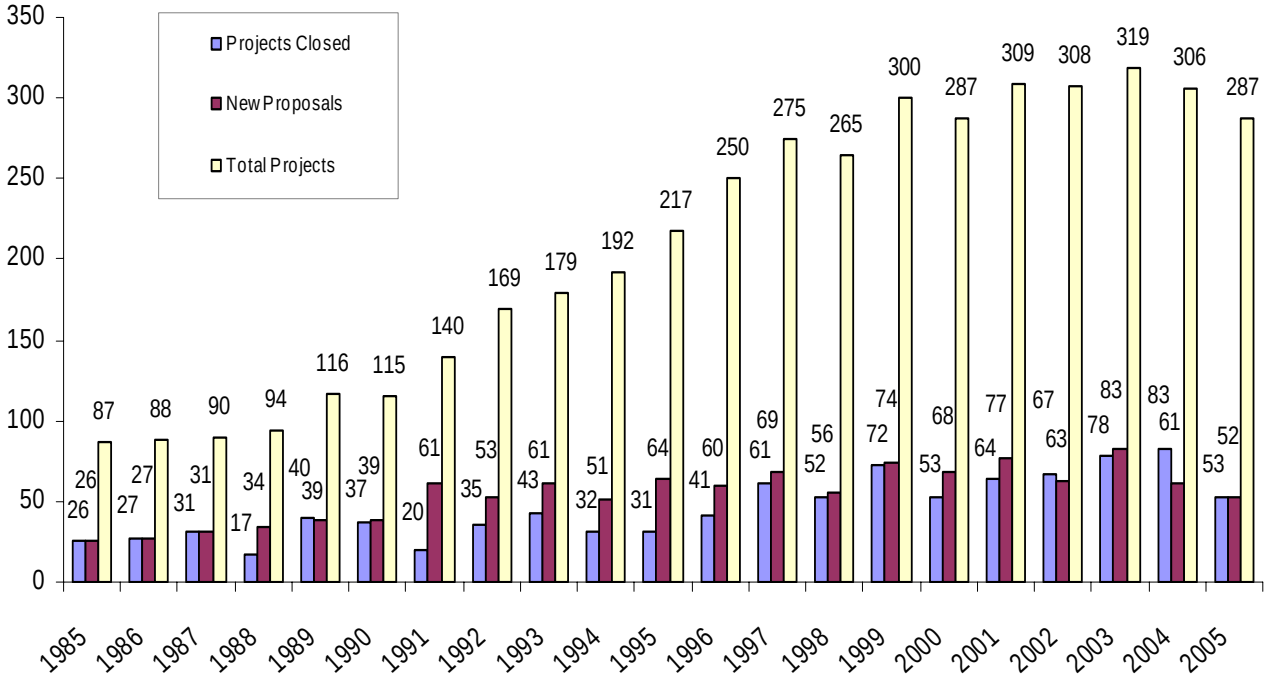


Figure 2 shows the distribution of new research proposals by agency and program for Fiscal Year 2005. The Department of Social and Health Services accounted for 53% of the new proposals reviewed during FY 2005. Children's Administration led DSHS program areas in the amount of research reviewed with 13% and Juvenile Rehabilitation Administration and Medical Assistance Administration each accounting for 10% of new proposals. About 41% of the new proposals reviewed were in the jurisdiction of the Department of Health, with 20% in Community and Family Health and 13% in Epidemiology and Health Statistics. Six percent of the proposals reviewed were in the jurisdiction of the Department of Labor and Industries.

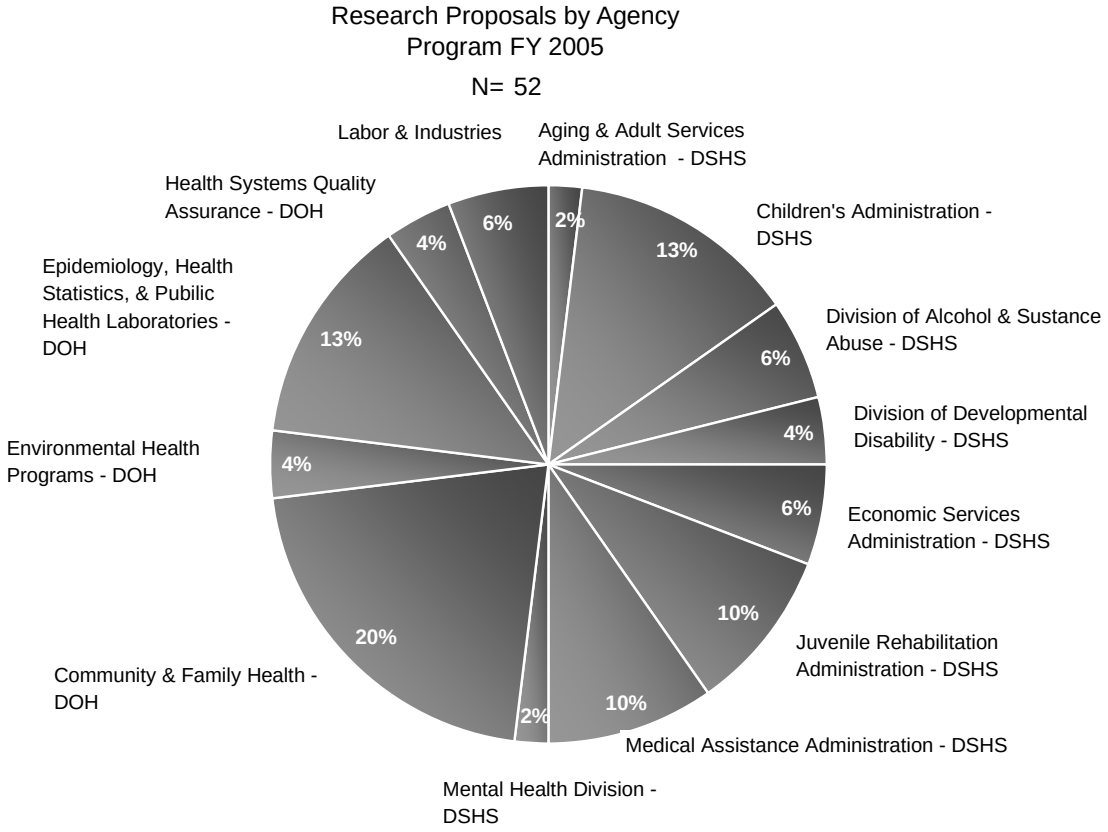
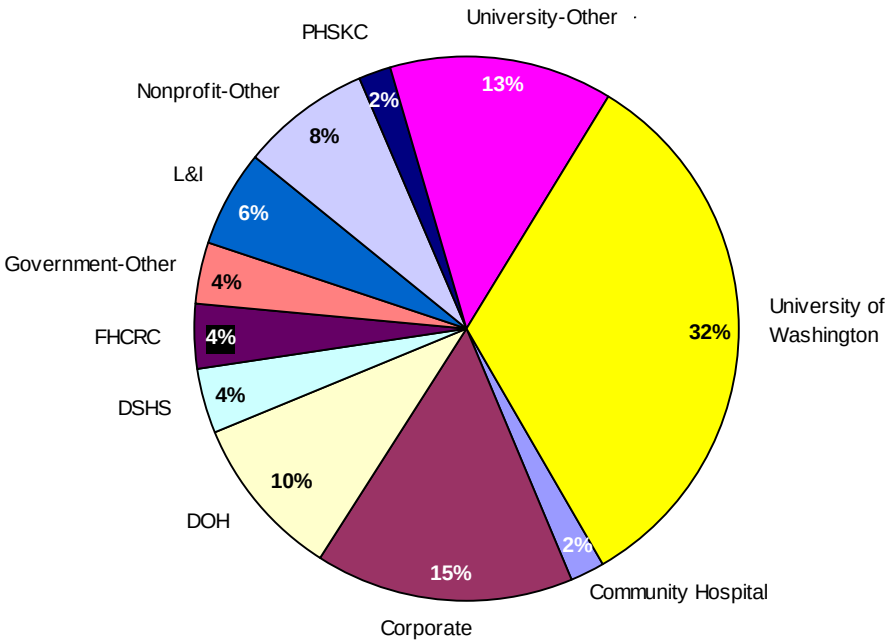


Figure 3 shows the organizational affiliation of the principal investigators for new research proposals received during Fiscal Year 2005. Almost 45% of the principal investigators were university-based, with the University of Washington accounting for the large majority.

Figure 3
Researchers Affiliation
FY2005
N=52



X. RESEARCH PROPOSALS: FISCAL YEAR 2005

New research proposals reviewed by the Board during Fiscal Year 2005 are listed in chronological order of receipt in the Project Log. These new proposals account for approximately one-quarter of the total number of ongoing research projects under the Review Board's jurisdiction at the end of Fiscal Year 2005.

Some examples of typical research conducted in the departments' jurisdiction are briefly described below. These projects are listed in the Project Log by the date of receipt, which is indicated by the numerical component in the Project Code. Projects discussed below are identified by the numerical component of the project code in parentheses.

Several research proposals reviewed during FY05 focused on the criminal justice system and programs for individuals who are or may become incarcerated. This included evaluations of family drug courts (B-072504-S), and evaluations of programs for youth on parole (B-092804), employment and skill-building programs for juvenile offenders (B-012605-S), and a mentoring program for youth leaving incarceration (B-061505-S). Other

research in the area of child health and welfare involved children and youth in foster care (A-101904-S, B-061005-S, A-061605-S. B-042805-S) or who were adopted (B-030905-S); dental health services (A-010705-S); immunizations (A-041805-H); appendicitis (B-011405-S); children with spina bifida (A-032305-S) and plagiocephaly (A-051305-H).

Graduate students continue to submit research proposals for WSIRB review, in a variety of subject areas. One project focused on an intervention to decrease television viewing among low-income children in pre-school ((A-081304-H). Other student research evaluated alcohol- and drug-exposed births to women in substance abuse treatment (A-011204-S), co-infection with HIV and Hepatitis C (B-011905-H), swallowing function among institutionalized mentally retarded persons (B-032805-S), and the lives of young children who use medical technology (B-042705-S).

Several research proposals on environmental health were submitted for review during FY05. Two studies evaluated fish consumption and related mercury exposure (A-072804-H, A-061705-H), while a University of Washington study focused on air pollution and the risk of respiratory illness among infants. Other public health research focused on HIV/AIDS (A-121604-H, A-012705-H), trauma patients (A-081204-H, A-110104-H), colorectal cancer (A-121704-H), and *Salmonella* transmission (A-050905-H).

The Department of Labor and Industries submitted proposals regarding a workplace occupational health and safety intervention, (A-021505-L), a program to reduce injuries in the trucking industry (A-042705-L), and an evaluation of injuries among hospital staff in relation to conflicts between work and personal life (A-060105-L).

The Human Research Review Section does not distribute final reports or other research products resulting from the studies under review. Information about the research listed in the Project Log, as well as research reports, should be requested directly from the principal investigator of each study.

PROJECT LOG

Research Proposals Reviewed by the Washington State Institutional Review Board during Fiscal Year 2005

PROJECT LOG KEY

Project Code

Prefix	Designates Review Board A, Review Board B, or Cooperative Review with another IRB
Number	Designates month, day, and year proposal received
Suffix	Designates state agency jurisdiction (S=DSHS; H=DOH; L=L&I; U=Unaffiliated, C=Cooperative review with another institution)

Program

Department of Social and Health Services

A&AS/ADSA	Aging and Adult Services/Aging and Disability Services
CA	Children's Administration
DASA	Division of Alcohol and Substance Abuse
DDD	Division of Developmental Disabilities
DVR	Division of Vocational Rehabilitation
ESA	Economic Services Administration
HRS	Health and Rehabilitative Services Administration
JRA	Juvenile Rehabilitation Administration
MAA	Medical Assistance Administration
MHD	Mental Health Division

Department of Health

CFH	Community and Family Health
EHS	Epidemiology, Health Statistics, & Public Health Laboratories
HSQA	Health Systems Quality Assurance
EHP	Environmental Health Programs

Department of Labor and Industries

SHARP	Safety and Health Assessment & Research for Prevention
PRS	Planning and Research Services

Unaffiliated Investigators

UNA	Research not in jurisdiction of WSIRB; reviewed at investigator request

Status

Ongoing	Project pending final approval, or approved and continuing
Cancelled	Project was discontinued
Completed	Project was finished
Suspended	Project approval suspended
Exempt	Project was reviewed and found to be outside of the WSIRB jurisdiction

Project Log
Activity Report
From 7/1/2004 thru 6/30/2005

Project Code	Project Title	Program	Status
B-072504-S	"Pierce County Family Drug Court Outcome Evaluation"	CA	Ongoing
	Claus Tjaden — Toucan Research (Vail, Colorado)		
A-072804-H	"Overexposure to Mercury in Members of the Asian/Pacific Islander Community"	EHP	Ongoing
	Koenraad Mariën — DOH / Office of Environmental Health Assessments		
B-072904-S	"King County Superior Court Reclaiming Futures Local Evaluation"	DASA	Ongoing
	Peter Selby — TriWest Group (Seattle, WA)		
B-080604-H	"Incidence of Infant Bronchiolitis and Particulate Matter Air Pollution"	EHS	Ongoing
	Jane Koenig — UW / Environmental & Occupational Health		
A-081204-H	"Interfacility Transfers in the Washington State Trauma Registry"	HSQA	Ongoing
	Danelle Wallace — UW / Harborview Injury Prevention and Research Center		
A-081304-H	"ClicKit! To Reduce Television in Early Childhood Study"	CFH	Ongoing
	Acacia Smith — UW / School of Public Health		
A-092104-S	"Evaluation of the Personal Assistant Recruitment and Retention Project (PARR)"	AAS	Completed
	Suzanne Sikma — UW / School of Nursing		
B-092804-S	"Washington State Functional Family Parole Evaluation Project"	JRA	Ongoing
	Thomas Sexton — Indiana University / Center for Family & Adolescent Studies		
B-092904-S	"Effects of Dialectical Behavior Therapy on an Adolescent Inpatient Population"	MHD	Ongoing
	Jon McClellan — DSHS Child Study and Treatment Center		
A-101904-S	"Foster Adolescents: What Resources Do Foster Families Need?"	CA	Ongoing
	Sandra Altshuler — EWU / School of Social Work		
A-102604-H	"Breast and Bone Follow-Up Study of the Fracture Intervention Trial"	CFH	Ongoing
	James Lacey, Jr. — NIH / National Cancer Institute		
B-102704-S	"The Multi-Site Evaluation of the Serious and Violent Offender Initiative"	JRA	Cancelled
	Pamela Lattimore — RTI International and Urban Institute		
A-110104-H	"International Comparison of Prehospital Trauma Care"	HSQA	Ongoing
	Bahman Roudsari — UW / Harborview Injury Prevention and Research Center		

Project Code	Project Title		Program	Status
C-110504-H	"Hagopian Laboratory Sample Repository"		CFH	Ongoing
	William Hagopian	Pacific Northwest Research Institute (Seattle, WA)		
A-111204-S	"Subsequent Alcohol and/or Drug Exposed Births in the Parent-Child Assistance Program"		DASA	Completed
	Gwyneth Moya	UW / School of Public Health (student)		
C-111604-H	"Prediction of Insulin-Dependent Diabetes in the General Population"		CFH	Ongoing
	William Hagopian	Pacific Northwest Research Institute (Seattle, WA)		
B-120104-S	"Functional Changes in Swallowing among Adults with Cerebral Palsy and Mental Retardation"		DDD	Cancelled
	Cynthia Willman	UW / Rehabilitation Medicine (graduate student)		
A-120204-S	"A Study of Alternative Co-Payments for Child Care Subsidies in Washington"		ESA	Ongoing
	Jean Layzer	Abt Associates (Cambridge, MA)		
B-121504-S	"Juvenile Ready4Work: An Ex-Prisoner, Community, and Faith Initiative Evaluation"		JRA	Cancelled
	Karen Walker	Public/Private Ventures (Philadelphia, PA)		
A-121504-H	"Steps to a Healthier US"		CFH	Ongoing
	Julia Dilley	DOH / Steps to a Healthier Washington Program		
A-121604-H	"National HIV Behavioral Surveillance"		CFH	Ongoing
	Hanne Thiede	Public Health - Seattle and King County		
A-121704-H	"Assessing the Public Health Impact of the Colorectal Cancer Direct-to Consumer Campaign"		CFH	Ongoing
	Deborah Bowen	FHCRC / UW		
A-122104-S	"Welfare to Work Analysis - Contingent Work"		ESA	Cancelled
	David West	Center for a Changing Workforce (Seattle, WA)		
A-010705-S	"Follow-up Assessment of Fluoride Varnish and Dental Care Use in Children"		MAA	Ongoing
	Charlotte Lewis	UW / Child Health Institute		
B-011205-H	"Improving the Care and Outcomes in Ovarian Cancer: A Population-Based Evaluation"		EHS	Ongoing
	Clifford Ko	UCLA / Division of General Surgery		
B-011405-H	"Abdominal Pain: Predictors of Appendicitis in Children"		EHS	Cancelled
	Carolyn Paris	Children's Hospital & Regional Medical Center (Seattle, WA)		
B-011905-H	"HIV/HCV Coinfection in Washington State Reported HIV/AIDS Cases"		CFH	Ongoing
	Tom Jaenicke	UW / School of Public Health		

Project Code	Project Title	Program	Status
B-012605-S	"Evaluation of the Gateways Program for Incarcerated Youth"	JRA	Ongoing
	Sylvie McGee — All for a Good Cause Consulting (Olympia, WA)		
A-012705-H	"Washington State HIV Incidence Surveillance"	CFH	Cancelled
	Maria Courogen — DOH / Infectious Disease and Reproductive Health		
A-021505-L	"Workplace Occupational Health and Safety Intervention"	SHAR	Ongoing
	Barbara Silverstein — L&I / SHARP		
A-022505-H	"Predicting Infant Sleep Position with PRAMS, Birth Certificate, and CHARS Data"	CFH	Ongoing
	Christy McKinney — UW / Department of Epidemiology		
B-030405-S	"Use of Dementia Medications by Chronically Institutionalized Medicaid Beneficiaries"	MAA	Ongoing
	Nancy Morden — UW / Dept of Family Medicine		
B-030905-S	"Strengthening Adoptive Families through Education (SAFE)"	CA	Ongoing
	Margaret McKenna — ConTEXT Sociocultural Research and Analysis		
A-031505-H	"Low Birthweight and Other Risk Factors for Hepatoblastoma"	EHS	Cancelled
	Logan Spector — University of Minnesota / Dept of Pediatrics		
A-031705-S	"Tiered Reimbursement Pilot Project Evaluation Comparison Group Study"	ESA	Ongoing
	Christopher Blodgett — Washington State University		
A-032305-S	"Healthcare Utilization, Expenditures, and Outcomes of Persons with Spina Bifida"	MAA	Ongoing
	Frederick Connell — UW / Child Health Institute		
B-032805-S	"Swallowing Abilities Among Adults with Severe and Profound Mental Retardation"	DDD	Completed
	Cynthia Willman — UW / Dept of Rehabilitative Medicine		
A-041805-H	"Vaccine Safety Surveillance and Assessment Activities"	EHS	Cancelled
	John Mullooly — Kaiser Permanente Northwest (Portland, OR)		
A-042505-S	"Linking the SEER Cancer Registry with Indian Health Service Records"	MAA	Ongoing
	Scott Ramsey — Fred Hutchinson Cancer Research Center		
A-042705-L	"Washington State Trucking Injury Reduction Emphasis through Surveillance (TIRES)"	SHAR	Ongoing
	Barbara Silverstein — L&I / SHARP		
B-042705-S	"Activity Settings and Daily Routines of Infants and Toddlers Assisted by Medical Technology"	MAA	Ongoing
	Dianne Rios — Boston University / Doctoral Candidate		

Project Code	Project Title		Program	Status
A-042805-S	"Measuring and Tracking Statewide Model Program Fidelity"		DASA	Cancelled
	Linda Becker	DSHS / DASA		
B-042805-S	"The Parent Mentoring Program"		CA	Ongoing
	Maureen Marcenko	UW / School of Social Work		
A-050905-H	"Dissemination of Zoonotic MDR-Salmonella"		EHS	Ongoing
	Tom Besser	WSU / Veterinary Microbiology and Pathology		
B-051005-S	"A Duration Analysis of Washington State TANF Spells"		CA	Ongoing
	Tomas Mosquera	Washington State University / Dept of Economics		
C-051005-H	"Development of Educational Messages for Women with High Risk Papillomavirus"		CFH	Ongoing
	Laura Koutsky	UW / Epidemiology		
A-053105-H	"Identifying Risk Factors for Plagiocephaly in Multiple Birth Sets"		EHS	Ongoing
	Christy McKinney	UW / Department of Epidemiology		
A-060105-L	"Linking Work-Family Conflict to Occupational Injuries among Hospital Employees"		SHAR	Pending
	Barbara Silverstein	L&I / SHARP		
B-061005-S	"Prevention Research with Infants in Foster Care"		CA	Ongoing
	Susan Spieker	UW / Family and Child Nursing		
B-061505-S	"Juvenile Ready4Work: An Ex-Prisoner, Community, and Faith Initiative"		JRA	Ongoing
	Wendy McClanahan	Public/Private Ventures (Philadelphia, PA)		
A-061605-S	"Finding Our Roots, Family Group Conferencing Evaluation Project"		CA	Ongoing
	Carol Harper	UW / School of Social Work		
A-061705-H	"Validating Fish Consumption Questions Among Women of Child-Bearing Age"		EHP	Ongoing
	James VanDerslice	DOH / Environmental Health		

Total Count: 52

Washington State
Department of Social
& Health Services

Research and Data Analysis Division
Report Number 11.127