

Activity Report
Washington State Institutional Review Board
Fiscal Year 2003

May 2004

ACTIVITY REPORT

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

WASHINGTON STATE INSTITUTIONAL REVIEW BOARD

Fiscal Year 2003

May 2004

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 # 11.97

DEPARTMENT OF SOCIAL AND HEALTH SERVICES

Dennis Braddock, 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.

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Michael A. Garrick, Ph.D.
Coordinator
DSHS Human Research Review Section

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Senior Research Associate
Washington Institute, Western Branch

Associate Executive Secretary

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Review Coordinator
DSHS Human Research Review Section

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DSHS Medical Assistance Administration

Danna Moore, Ph.D.
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WSU Social and Economic Sciences Research Center

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Associate Medical Director – SHARP
Department of Labor & Industries

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

Steve Bowman, M.H.A.
Manager, Research and Data Analysis
DOH Emergency Medical and Trauma Prevention

Robert Morasky, Ph.D.
Field Services Psychologist
DSHS Division of Developmental Disabilities

Pat deHart, Sc.D.
Epidemiologist
DOH Immunization Project

Melanie Payne, M.P.H.
Epidemiologist
Southwest Washington Health District

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

Jesús Reyna, R.N., B.S.N.
Consultant
HIV/AIDS Health Services

Martha Holliday, M.P.H.
Program Manager
DSHS Children's Administration

James VanDerslice, Ph.D.
Environmental Epidemiologist
DOH Environmental Health Programs

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

George Yeannakis, J.D.
Prisoner Representative

WASHINGTON STATE INSTITUTIONAL REVIEW BOARD B

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Margaret Frederick, M.P.H.
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DSHS Human Research Review Section

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Research Investigator
DOH Center for Health Statistics

John Steiger, Ph.D.
Senior Forecaster
Caseload Forecast Council

Chris Blodgett, Ph.D.
Associate Scientist
WSU Department of Human Development

Hanne Thiede, D.V.M., M.P.H.
Senior Epidemiologist
Seattle-King County Dept of Public Health

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Community Representative

John Thompson, M.P.A.
Community Representative

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

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

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

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

Rachael Fantz, Pharm.D., B.C.P.P.
Clinical Geropsychiatric Pharmacist
Western State Hospital

George Yeannakis, J.D.
Prisoner Representative

Barbara Burns McGrath, Ph.D.
Research Associate Professor
UW School of Nursing

Alternates:

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

Megan Rutherford, Ph.D.
Research Scientist
UW Alcohol and Drug Abuse Institute

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

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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 2003. 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) 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 2003

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 housed in the Department of Social and Health Services is the IRB for the three state agencies.

The Washington State Institutional Review Board has primary responsibility for implementing the departments' human subjects protection policy. The Review Board 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 must also determine that 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 with 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, public health, and alcohol and substance abuse proposals but also reviews other areas of research.

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 research 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. Occasionally, the researcher is invited to attend the meeting to respond to questions or concerns or to provide supplementary information.

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*, published by the Review Section and on the website, as a checklist 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.

VIII. MAJOR ACTIVITIES: FISCAL YEAR 2003

Human Subject Protection Activities at the National Level

In 2003, the Institute of Medicine (IOM) conducted an evaluation of the system for human subjects protection, at the request of DHHS. IOM began its evaluation of the human subjects protection system after the death of Jesse Gelsinger during a gene transfer trial at the University of Pennsylvania. In its report, published in October 2003, the IOM recommended broader federal oversight which would involve the protection of *all* participants in research, regardless of funding source. The IOM report includes recommendations for improving human subjects protection and calls for development of standards for evaluating quality assurance and quality improvement of the human subjects protection system. The IOM also recommended establishing a fund to compensate subjects who are injured as a result of their participation in research and increasing financial support for IRBs. The report is entitled *Responsible Research: A Systems Approach to Protecting Research Participants* and is available at <http://www.iom.edu/report.asp?id=4459>.

The Privacy Rule, which took effect on April 14, 2003, adds new privacy protections for subjects involved in research. The Rule specifies criteria that must be met for an IRB to approve waiver of the subject's written authorization for use or disclosure of his or her protected health information in research (45 CFR 164.512(i)). The Rule also specifies several new requirements for information that must be in a valid authorization form for use or disclosure of protected health information (45 CFR 164.508). Additional information is found in the document: [Privacy Rule – Requirements for Research](#) found on the Review Section's website.

The focus on conflict of interest in research has shifted to IRBs. The Association of American Medical Colleges recommended that IRB members report on any financial

conflicts of interest when the institution receives funds from commercial sponsors of research. Universities in particular receive millions of dollars in funds from the biotech industry, the pharmaceutical industry, and other enterprises. The AAMC advises that financial conflicts among IRB members should be disclosed prior to review of individual research proposals.

In March 2003, DHHS issued draft guidance on managing financial conflict of interest in human subjects research. The guidance focuses on whether financial considerations may harm the rights and welfare of research participants. The document also contains specific provisions for IRBs, including asking members if they have any such conflicts and documentation in meeting minutes that members with a possible conflict did not participate in the discussion or vote on the specific proposal with which there may be a conflict. The document, which is entitled “Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection” is available at: <http://ohrp.osophs.dhhs.gov/references/fr03-7691.pdf>.

In late spring 2003, NIH issued the final data sharing policy for research it sponsors. Beginning in October 2003, researchers requesting more than \$500,000 in funds for direct costs in a single year must describe a plan for sharing final research data, or explain why data sharing is not possible. The data sharing policy is consistent with HIPAA Privacy Rule requirements, and states that data intended for use by other parties should be free of identifiers that would permit even deductive identification of individual research subjects. The “NIH Data Sharing Policy and Implementation Guidance” is available on the NIH website.

In July 2002, OHRP issued revised guidance on continuation review of research. The guidance provides a definition for “substantive and meaningful review”; considerations for continuation review of multi-center clinical trials which include a Data Safety and Monitoring Board (DSMB); defining when expedited review procedures are appropriate; how to determine the continuation approval date; and procedures to follow in the event study approval lapses. The guidance also delineates when review of informed consent documents should occur. OHRP also issued guidance on development of written procedures for IRB operations. Written procedures should cover all regulatory requirements in 45 CFR 46 for documentation of IRB deliberations and actions. The guidance was developed in part as a result of findings of for-cause audits of IRBs and their home institutions.

Human Subject Protection Activities at the Local Level

At the beginning of FY 2003, the name of the Review Board changed to the Washington State Institutional Review Board (WSIRB). The name change reflects a trend toward the Board reviewing research for a growing number of state and local agencies. The new name also is consistent with how the Board is identified at local academic and research institutions, where it is commonly known as the “State IRB.”

DSHS sponsored House Bill 1622 during the 58th legislative session. The bill proposed to revise RCW 42.48 to include the Department of Labor and Industries; to make a technical revision to allow state agencies to designate an IRB, rather than establish their own; to change the definition of research to be compatible with 45 CFR 46; and to broaden

protections for researchers from forcible disclosure of identifiable research information. The Coordinator of the Review Section testified at hearings before the House Long Term Care Committee, along with a representative from the Department of Labor and Industries. After opposition from stakeholders in the final days of the session, the bill to revise RCW 42.48 failed to pass out of committee.

The *Washington State Agency Policy on Protection of Human Research Subjects* was revised in April 2003 to incorporate two new chapters regarding waivers and disclosure authorizations under HIPAA, and to revise a chapter regarding waiver of consent for disclosure of state agency records. The revised policy was approved by all three state agencies for which the Board conducts human subjects reviews. The revised *Policy* is available on the Review Section website.

Effective July 1, 2002, all WSIRB members, staff, and principal investigators are required to complete training in the protection of human research subjects. Training requirements may be fulfilled by documenting completion of training at the researcher's home institution, by taking in-person tutorials sponsored by the University of Washington, or by completing the online course developed by the Collaborative IRB Training Initiative (CITI) and available on the Section's website: <http://www1.dshs.wa.gov/rda/hrrs/training.shtml>. Online CITI training in the protection of human research subjects is available at no cost to all employees of the Department of Social and Health Services, the Department of Health, and the Department of Labor and industries.

Late in FY 2002, Review Section staff met with the two Board Chairs to evaluate Board procedures and to identify areas for improvement. From this meeting, plans were developed to launch a Quality Improvement Initiative for the Review Board. The Initiative focused on improving the quality of proposals reviewed by the full Board by conducting pre-reviews of all proposals before the meeting, and on increasing the efficiency and effectiveness of the meetings by adopting and following modified *Roberts Rules of Order*.

In response to the Quality Improvement Initiative, the Review Section implemented enhanced pre-review procedures for proposals submitted for full Board review. Pre-review is an administrative screening process intended to identify missing information or incomplete sections in proposals that would cause delays in the review process. Pre-review also is intended to identify questions and/or issues that likely would be raised during full Board review and that could result in delay of a disposition decision until a written response from the investigator is received. The pre-review is conducted by the primary reviewer and Review Section staff, and investigators are informed in writing of issues that should be addressed before the full Board review. By addressing these issues in a revised application, the investigator has the opportunity to increase the likelihood of favorable review disposition during the Board meeting. To the extent that pre-review is successful in improving the quality of proposals considered at the meetings, it also reduces the workload of Review Board members.

To assist the primary reviewer in presenting the proposal in the meeting, the Review Worksheet was revised and expanded to include all the information needed for the Review Board to reach a decision on the proposal. The modified *Robert's Rules* encouraged an environment in which the primary reviewer could make a comprehensive presentation to the Board, including a recommendation for disposition of the proposal, without being interrupted by comments from other Board members. When the primary reviewer finishes

the presentation, the Board Chair recognizes all members who have comments on specific aspects of the proposed research, which allows a more orderly consideration of the most important issues and concerns. If the primary reviewer wishes to modify or withdraw the disposition recommendation based on the additional comments from other members, the modified *Robert's Rules* provides for this contingency.

After four meetings, Board members were surveyed to evaluate whether the Quality Improvement Initiative improved the quality of proposals submitted for review, the presentation of proposals by primary reviewers, and the overall management of meetings. Survey findings from both Boards provided strong support for the enhanced pre-review procedures and for adoption of modified *Roberts Rules*. Most Board members preferred the more structured meeting format, although some members voiced concern that too much reliance on *Robert's Rules* may stifle or restrict discussion in the meeting. The revised Review Worksheet also was well received.

The Research Application forms were revised and updated in May 2003. A specific form was developed to obtain information from researchers that addresses the applicable criteria in federal regulations ([45 CFR 46.116\(d\)](#) and [45 CFR 164.512\(i\)](#)) and state law ([RCW 42.48.020\(2\)\(a\)](#)) and [RCW 70.02.050\(g\)](#)) for disclosure of identifiable personal records and/or protected health information without written consent or authorization. Researchers must explain how their proposed study satisfies each of these criteria before the WSIRB will approve waiver of authorization for use or disclosure of individually identifiable personal records or protected health information.

In the spring of 2003, the Review Section began to ask researchers to be available by telephone during Board deliberations of their proposals. If questions or concerns arise during the meeting that cannot be addressed by the primary reviewer and/or Review Section staff, the researcher can be put on a speaker phone to provide additional information. By addressing these issues during the meeting, the Board may be able to reach a disposition decision rather than deferring a decision to a subsequent meeting.

In February 2003, Review Section staff and two Review Board members conducted a site visit to Echo Glen Children's Center. The site visit was conducted in order to consult with DSHS Juvenile Rehabilitation Administration (JRA) staff regarding the human subjects review process and to identify issues and/or problems specific to the institution. The site visit facilitated review of research involving youth offenders, as it strengthened collaboration with facility staff and enhanced understanding of the facility, programs available to incarcerated youth, and the particular issues these youth face in their lives. Review Section staff will conduct site visits to other DSHS institutions in the future.

In the Spring of 2003, Review Section staff in conjunction with a contracted consultant began to revise and expand the Review Board's written procedures to better meet the requirements in the federal human subjects protection regulations. The WSIRB Procedures Manual describes the Board's procedures for conducting initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research during the period for which IRB approval has already been given may

not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject. Procedures also cover reporting of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with agency policy or the requirements or determinations of the IRB and any suspension or termination of IRB approval. By the end of FY 2003 when the consultant's contract was completed, a good working draft of the WSIRB Procedures Manual was available for editing and completion by Review Section staff.

Review Section staff developed draft forms for requesting study amendments and for reporting adverse events and unanticipated problems which pose risks to subjects. During the latter part of FY 2003, the two forms were "beta tested" with researchers who requested amendments or who had unanticipated problems to report to the Review Board. The forms will be finalized and made available on the Review Section website when the WSIRB Procedures Manual is adopted and published in FY 2004.

The Review Section website address changed to: <http://www1.dshs.wa.gov/rda/hrrs/>. The website was updated to include a worksheet for 45 CFR 46 Subpart B, Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research. The worksheet will be used to evaluate proposals which include pregnant women and to document that the proposed research meets the requirements in the regulations. A Handbook page was added to the website for the use of WSIRB members. All the forms and worksheets need by Review Board members are consolidated on the new Handbook page.

Public Responsibility in Research and Medicine (PRIM&R) and the Applied Research Ethics National Association (ARENA) sponsored a conference in Seattle on August 15-16, 2002. Nine members from both Boards attended "Protecting Human Subjects: Safety, Welfare, and Privacy". A Review Section staff member presented "Privacy and Confidentiality in Research" at the conference.

Dr. Marcia Goldoft resigned from the Board after 10-years of service. The Secretary of DSHS appointed Dennis McBride, Ph.D., as the new Chair of Review Board A.

The Review Section prepared and distributed *IRB Handbooks* to all Review Board members. The *Handbooks* contain reference materials, worksheets, Board meeting information, and other materials to assist Board members in review of proposals.

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 1983 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 66% during the most recent ten-year period, from 192 in 1994 to 319 in 2003.

Figure 1
Review Volume
Fiscal Years 1983 - 2003

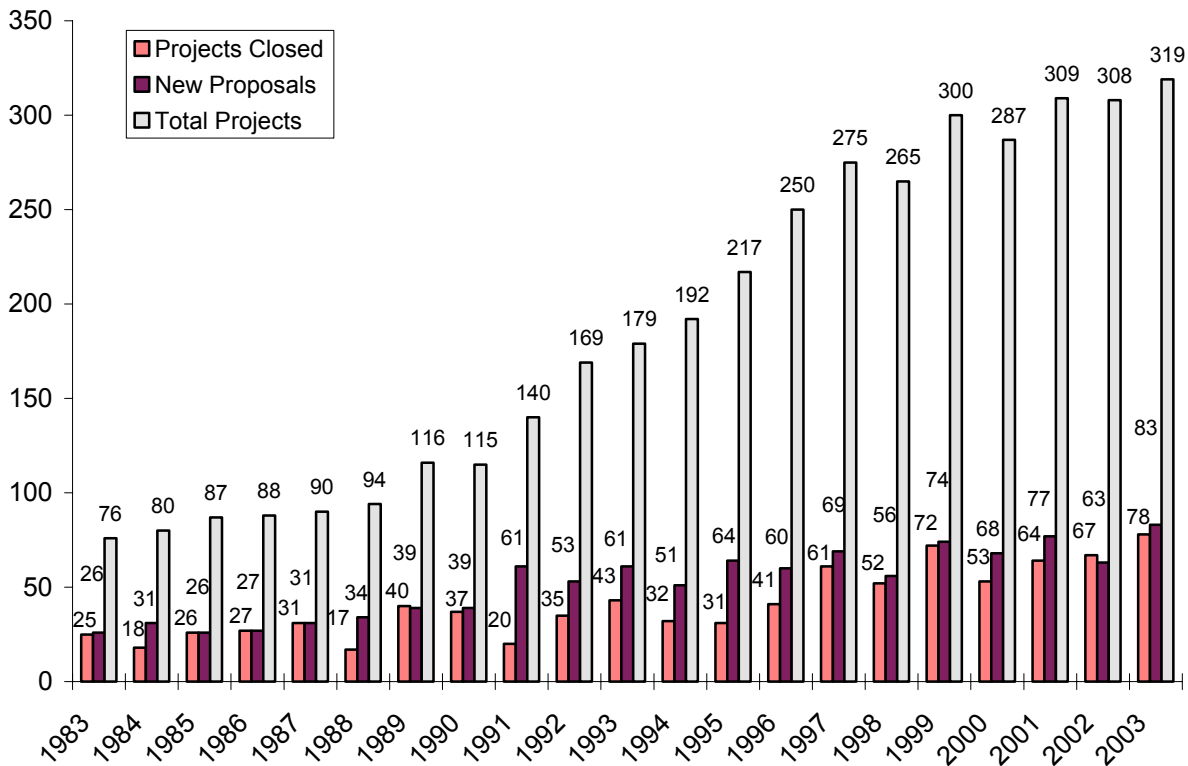


Figure 2 shows the distribution of new research proposals by agency and program for Fiscal Year 2003. The Department of Social and Health Services accounted for about 50% of the new proposals reviewed during FY 2003. Children's Administration, with 13% of the total, and Juvenile Rehabilitation Administration with 11% of the total, led DSHS program areas in the amount of research reviewed. About 40% of the new proposals reviewed were in the jurisdiction of the Department of Health, with 18% in Community and Family Health and 16% in Epidemiology and Health Statistics. Four percent of the proposals reviewed were in the jurisdiction of the Department of Labor and Industries, and 6% were from other institutions and were reviewed at their request although they were not in the jurisdiction of DSHS, DOH or L&I.

Figure 2
 Research Proposals by Agency Program
 FY 2003
 N=83

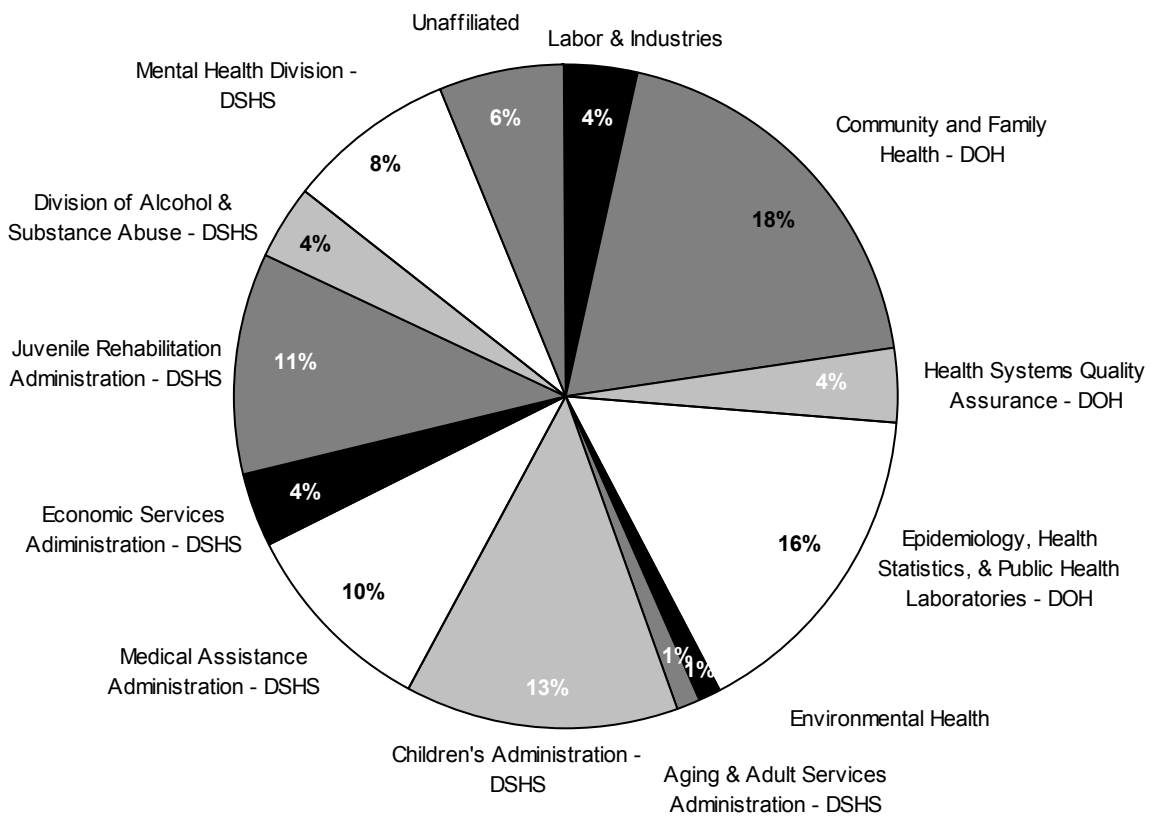
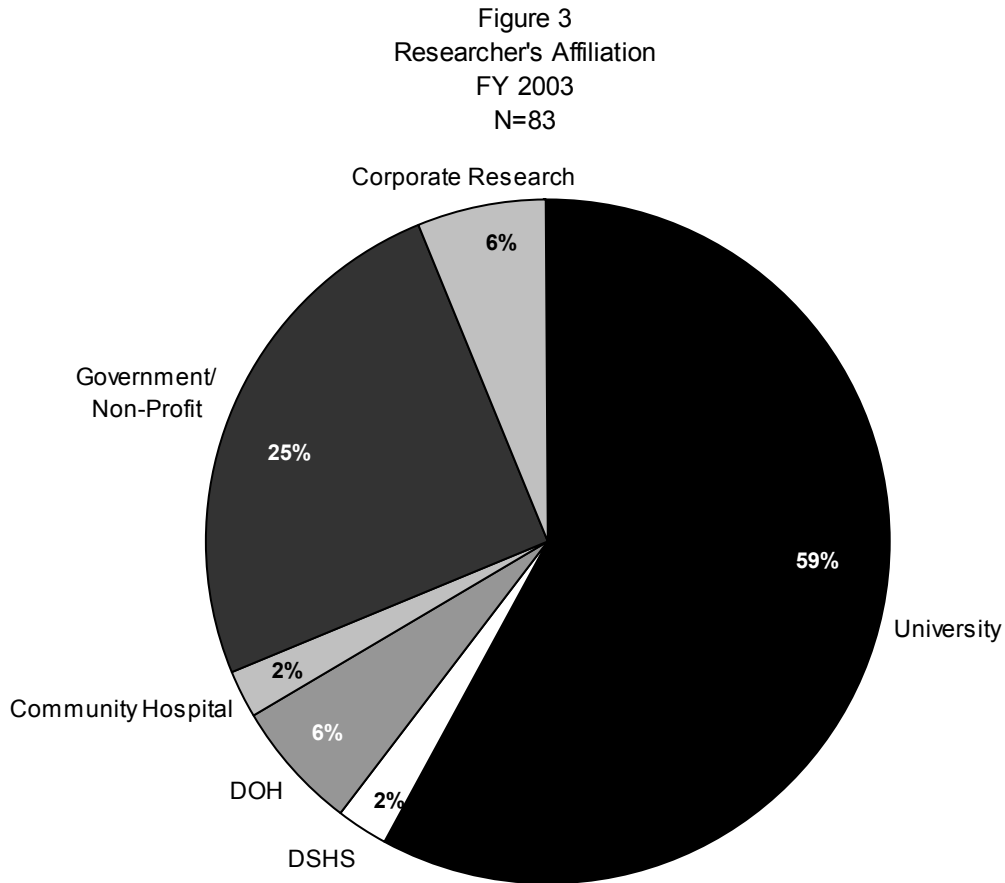


Figure 3 shows the organizational affiliation of the principal investigators for new research proposals received during Fiscal Year 2003. Almost 60% of the principal investigators were university-based, with the University of Washington accounting for the large majority.



X. RESEARCH PROPOSALS: FISCAL YEAR 2003

New research proposals reviewed by the Board during Fiscal Year 2003 are listed in chronological order of receipt in the Project Log. These new proposals account for approximately one-third of the total number of ongoing research projects under the Review Board's jurisdiction at the end of Fiscal Year 2003.

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.

Many of the studies which requested disclosure of confidential DSHS records focused on quality of care for Medicaid clients, ranging from studies of dental health care (B-082902-S, B-103002-S, B-040803-S), to costs of services for blind and disabled clients (A-091602-S), children with chronic conditions (A-112202-S), homeless persons (A-121702-S), and depression among children (A-062503-S).

Other DSHS-related projects focused on incarcerated youth (B-091902-S, B-110102-S, B-120502-S, B-051203-S, A-061703-S), persons diagnosed with a mental illness (B-091002-S, B-032403-S, B-042803-S, B-061703-S, B-061803-S, B-063003-S), and child welfare (A-073002-S, A-100302-S, B-120402-S, A-012903-S, B-040703-S, B-040903-S, B-061603-S).

Research within the Department of Labor & Industries included a study of the workers compensation program (A-022503-L), short- and long-term disability among workers (A-042403-L), and the health and employment outcomes of apprentice workers (B-082602-L).

Proposals within Community and Family Health comprised the majority of DOH research reviewed by the WSIRB in FY 2003. These projects focused on cancer (A-070102-H, B-022803-H, A-062703-H), infectious and communicable diseases (A-081302-H, B-020103-H, A-021003-H, B-060603-H), genetics (B-122302-H), family planning (A-012703-H), and an intervention to prevent falls among the elderly (A-042503-H).

Epidemiology and Health Statistics continues to be a major source of research within DOH. Some of these studies involved linkage of DOH records to other data sources to evaluate maternal and child health (A-081402-H, A-102902-H, B-111302-H, A-041703-H, A-051903-H) and quality of care for stroke patients (A-040403-H). Other studies which involved contact with human subjects explored marketing of a genetic test (B-012403-H) and SARS (A-060503-H).

The WSIRB also reviewed federally funded research for other institutions, which had requested human subjects review and named the WSIRB as the IRB of record in their FWA with the federal Department of Health and Human Services. These studies focused on family planning (B-121802-U), meningococcal disease (A-080502-U), and antiretroviral drug resistance in HIV (B-013003-U).

The Review Board continues to review a variety of research projects from students, most of whom are graduate students in public health and social work, as well as students in other areas of the social and health sciences. Student research over the past fiscal year involved an analysis of worker disability (A-042403-L), maternal morbidity and preterm birth (A-080602-H), juvenile offenders (B-082202-S, B-091702-S), referrals to Child Protective Services (A-082902-S), clinical profiles of the elderly (A-092002-S), an evaluation of DSHS employees (A-110202-S), the workers compensation program (A-022502-L), cancer (B-031703-H), public assistance programs (A-040303-S), and infant health (B-052203-H).

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 2003**

PROJECT LOG KEY

Project Code

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

Program

Department of Social and Health Services

A&AS	Aging and Adult 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
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
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Status

Ongoing	Project pending final approval, or approved and continuing
Canceled	Project was discontinued
Completed	Project was finished
Suspended	Project activity on hold
Exempt	Project was reviewed and found to be outside of the HRRB jurisdiction

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2003 Status
A-070102-H	"Extended Follow-up of the Rocketdyne Worker Cohort", Beate Ritz, M.D., Ph.D., University of California-Los Angeles School of Public Health	CFH	Ongoing
B-072402-H	Racial Misclassification among American Indians and Alaska Natives in State Registries", Paul A. Stehr-Green, Dr.P.H., M.P.H., Northwest Portland Area Indian Health Board	CFH	Ongoing
A-073002-S	"Domestic Violence Fatality Review: Phase II", Margaret Hobart, M.A., Washington State Coalition against Domestic Violence	CA	Canceled
B-080102-S	"Evaluation of Continuity of Psychiatric Care in a Community Setting", Clarke St. Dennis, Ph.D., Washington State University College of Pharmacy	MHD	Canceled
B-080202-S	"Co-Morbid Psychiatric Disorders in Adolescent Sex Offenders", Vida Janson, M.D., University of Washington Department of Psychiatry & Behavioral Sciences	JRA	Canceled
A-080502-U	"Risk Factors for Invasive Meningococcal Infection Among Students in Grades 9-12", Karen R. Steingart, M.D., M.P.H., Clark County Health Department	UNA	Ongoing
B-080602-H	"Maternal Morbidity and Preterm Birth during Influenza Season", Lisa Lindsay, M.P.H., University of North Carolina, Chapel Hill	EHS	Ongoing
A-081302-H	"Association of Influenza Varicella with Chronic Health Conditions in Hospitalized Children in Washington State", Shervin Churchill, M.P.H., Children's Regional Hospital & Medical Center, Seattle, WA	CFH	Completed
A-081402-H	"Pilot Study of Airbags in Pregnancy", Melissa A. Schiff, M.D., M.P.H., Harborview Injury Prevention & Research Center	EHS	Canceled
B-082202-S	"Assessing Resilience in Juvenile Offenders and Non-Offending Peers", Jill E. Breitbach, M.S., Pacific University, Forest Grove, OR	JRA	Canceled

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2003 Status
B-082602-L	"Feasibility of Matching Administrative Database Records from Multiple Washington Sources", Elyse Ann Biddle, M.S., National Institute for Occupational Safety and Health	PRS	Canceled
A-082902-S	"An Exploratory Study of Referrals within DCFS Region 2", Dorene Perez, Eastern Washington University	CA	Canceled
B-082902-S	"The Primary Care Provider and Preventive Oral Health", Charlotte W. Lewis, M.D., M.P.H., University of Washington Department of Pediatrics	MAA	Ongoing
B-090302-S	"Effectiveness of Specialized Treatment for Women with Children--Qualitative Study", Robert G. Orwin, Ph.D., Westat, Rockville, MD	DASA	Ongoing
B-091002-S	"Evaluation of Continuity of Psychiatric Care in a Community Setting", Clarke St. Dennis, Ph.D., Washington State University College of Pharmacy	MHD	Ongoing
A-091202-H	"Failure of Nonoperative Management of Splenic Injuries: Causes and Consequences", Gregory J. Jurkovich, M.D., Harborview Medical Center Department of Surgery	HSQA	Canceled
A-091602-S	"Cost and Use Trends in Outpatient Services among Medicaid Blind and Disabled Participants", Stephen C. Lerch, Ph.D., Washington State Institute for Public Policy	MAA	Completed
A-091702-H	"TCE Exposure Assessment", Jan C. Semenza, Ph.D., M.P.H., Portland State University	CFH	Canceled
B-091702-S	"Perceptions of Adolescent Males Who Have Been Convicted of Homicide or Aggravated Assault", Paul E. Jordan, M.A., M.S., Argosy University, Seattle, WA	JRA	Disapproved
B-091902-S	"Survey of Youth in Residential Placement", Andrea J. Sedlak, Ph.D., Westat, Rockville, MD	JRA	Ongoing

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2003 Status
A-092002-S	"An Analysis of Clinical Dimensions of Older Adults Residing in Adult Family Homes", Robin Bonifas, L.I.C.S.W., University of Washington School of Social Work	A&AS	Canceled
B-092002-S	"Co-Morbid Psychiatric Disorders in Adolescent Sex Offenders", Vida Janson, M.D., University of Washington Department of Psychiatry & Behavioral Sciences	JRA	Canceled
A-092302-S	"Family Group Conference Evaluation Project", Michael Horn, Ph.D., University of Washington School of Social Work	CA	Canceled
A-092402-H	"Risk Factors for Invasive Meningococcal Infection Among Students in Grades 9-12: State Survey", Kathryn Lofy, M.D., Department of Health Public Health Laboratories	EHS	Ongoing
A-100302-S	"Fatherhood in the Child Welfare System Project", Diana J. English, Ph.D., Department of Social and Health Services Children's Administration	CA	Ongoing
A-102802-U	"Improving Family Planning and Reproductive Health Services for Individuals with Limited English Proficiency", David N. Fine, Ph.D., Center for Health Training, Seattle, WA	UNA	Canceled
A-102902-H	"Finding All Mothers' Experiences", Kellie Ragan, M.A., Jefferson County Health & Human Services	EHS	Canceled
B-103002-S	"Baseline Assessment of Fluoride Varnish Use in Children", Charlotte W. Lewis, M.D., M.P.H., University of Washington Department of Pediatrics	MAA	Ongoing
A-103102-S	"Family Group Conference Evaluation Project", Michael Horn, Ph.D., University of Washington School of Social Work	CA	Canceled
B-110102-S	"Co-Morbid Psychiatric Disorders in Adolescent Sex Offenders", Vida Janson, M.D., University of Washington Department of Psychiatry & Behavioral Sciences	JRA	Ongoing

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2003 Status
A-110202-S	"Employee's Resistance to Change: A Study within the Division of Child Support", Arel Johnson, St. Martin's College, Lacey, WA	ESA	Canceled
B-111302-H	"Fetal Deaths, Malformations, and Proximity to Hazardous Waste Sites in Washington", Beth Mueller, Dr.P.H., University of Washington Department of Epidemiology	EHS	Ongoing
A-112202-S	"Physician Networks and Children with Chronic Conditions", David Grembowski, Ph.D., University of Washington Department of Health Services	MAA	Canceled
B-112502-S	"Impact of Financing on Outcomes of Methadone Maintenance", Dennis Deck, Ph.D., RMC Research Corporation, Portland, OR	DASA	Ongoing
B-120402-S	"Factors Affecting Outcomes in Child Dependency and Termination Cases", Marna Geyer Miller, Ph.D., Washington State Institute for Public Policy	CA	Ongoing
B-120502-S	"Mental Health and Juvenile Justice: Building an Effective Model for Service Delivery", Eric W. Trupin, Ph.D., University of Washington Division of Public Behavioral Health and Justice Policy	JRA	Ongoing
A-121702-S	"A Program of Medical Respite and Health Care Outcomes and Costs among Homeless Persons", Thomas Rea, M.D., M.P.H., University of Washington Department of Medicine	MAA	Canceled
A-121802-U	"Improving Family Planning and Reproductive Health Services for Individuals with Limited English Proficiency", David N. Fine, Ph.D., Center for Health Training, Seattle, WA	UNA	Ongoing
B-121902-U	"Antiretroviral Drug Resistance Testing (ARVDRT) Pilot Surveillance Project", Sharon G. Hopkins, D.V.M., M.P.H., Public Health-Seattle & King County	UNA	Canceled
A-122002-S	"Family Group Conference Evaluation Project", Michael Horn, Ph.D., University of Washington School of Social Work	CA	Canceled

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2003 Status
B-122002-H	“Assessing the Public Health Impact of the Direct-to-Consumer Marketing for Genetic Testing for Breast & Ovarian Cancer Susceptibility”, Melanie F. Myers, Ph.D., M.S., Centers for Disease Control & Prevention	EHS	Canceled
B-122302-H	“Awareness of Genetic Health Care Services”, Debra Lochner Doyle, M.S., Department of Health Maternal and Child Health	CFH	Ongoing
B-012403-H	“Assessing the Public Health Impact of the Direct-to-Consumer Marketing for Genetic Testing for Breast & Ovarian Cancer Susceptibility”, Melanie F. Myers, Ph.D., M.S., Centers for Disease Control & Prevention	EHS	Ongoing
A-012703-H	“Impact of Family Planning Services Availability”, David C. Goodman, M.D., M.S., Dartmouth Medical School	CFH	Ongoing
A-012803-H	“TCE Exposure Assessment”, Jan C. Semenza, Ph.D., M.P.H., Portland State University	CFH	Canceled
A-012903-S	“Family Group Conference Evaluation Project”, Karin Gunderson, M.S.W., University of Washington School of Social Work	CA	Ongoing
B-013003-H	“Antiretroviral Drug Resistance Testing (ARVDRT) Pilot Surveillance Project”, Susan E. Buskin, Ph.D., M.P.H., Public Health-Seattle & King County	UNA	Ongoing
A-013103-H	“Well Water Quality and Infant Health Study”, James VanDerslice, Ph.D., Department of Health Office of Environmental Health Assessments	EHP	Ongoing
B-020103-H	“Survey of HIV Disease and Care Plus Interview (SHDC+)”, Susan E. Buskin, Ph.D., M.P.H., Public Health-Seattle & King County	CFH	Ongoing
A-021003-H	“Identification of Pertussis Transmission Sources among Infants Aged <4 Months in the US”, Charla A DeBolt, R.N., M.P.H., Public Health-Seattle & King County	CFH	Ongoing

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2003 Status
A-022503-L	"Evaluating Cost Effectiveness of Monitoring and Enforcement in Mandatory Workers Compensation Insurance", Candria Lee Rauser, University of Washington Interdisciplinary Arts & Sciences	SHARP	Ongoing
B-022803-H	"Validation of a Family History of Cancer Questionnaire for Risk Factor Surveillance", Louise Wideroff, Ph.D., National Cancer Institute	CFH	Canceled
A-030303-S	"Physician Networks and Children with Chronic Conditions", David Grembowski, Ph.D., University of Washington Department of Health Services	MAA	Ongoing
B-030503-S	"Improving Treatment Outcome through Program Evaluation", Alice Huber, Ph.D., University of Washington Alcohol & Drug Abuse Institute	DASA	Canceled
A-031103-H	"General Population HIV/AIDS Knowledge, Attitudes, and Beliefs (KAB) Survey", Todd Rime, M.A., Department of Health Infectious Disease & Reproductive Health	CFH	Ongoing
B-031203-S	"Welfare-to-Work Housing Voucher Evaluations", Gregory B Mills, Ph.D., Abt Associates, Cambridge, MA	ESA	Ongoing
B-031703-H	"Bladder Cancer and Socioeconomic Status in Washington", Alan Dabney, M.S., University of Washington Department of Biostatistics	CFH	Ongoing
B-032403-S	"Evaluation of Continuity of Gero-Psychiatric Care in a Community Setting", Peggy Odegard, Pharm.D., University of Washington School of Pharmacy	MHD	Ongoing
A-040303-S	"Welfare Dependency and Labor Force Participation", Dan Axelsen, Washington State University	ESA	Ongoing
A-040403-H	"Administrative Data and Quality of Care Research in Stroke", David Tirschwell, M.D., M.Sc., University of Washington Department of Neurology	EHS	Ongoing

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2003 Status
B-040703-S	"Increasing Foster Child Enrollment in Early Learning", Abraham B. Bergman, M.D., Harborview Medical Center	CA	Ongoing
B-040803-S	"Access to Orthodontic Care for Children with Cleft Lip and/or Palate", Charlotte W Lewis, M.D., M.P.H., University of Washington Department of Pediatrics	MAA	Ongoing
B-040903-S	"Unified Family Court Pilot Project Evaluation", Barbara A Lucenko, Ph.D., Administrative Office of the Courts	CA	Ongoing
A-041703-H	"Accuracy of Fetal Death Certificate Records", Mona Lydon-Rochelle, Ph.D., M.P.H., University of Washington School of Nursing	EHS	Ongoing
A-042403-L	"Primary and Secondary Predictors of Workplace Disability", Bert Stover, University of Washington Department of Health Services	SHARP	Ongoing
A-042503-H	"Senior Falls Prevention Study", Mary LeMier, M.P.H., Department of Health Injury Prevention Program	CFH	Ongoing
B-042803-S	"Long-Term Outcomes of Mental Health Division Clients", Stephen C. Lerch, Ph.D., Washington State Institute for Public Policy	MHD	Ongoing
B-051203-S	"National Norms for the MAYSI-2", Thomas Grisso, Ph.D., University of Massachusetts Medical School	JRA	Ongoing
A-051903-H	"Geographies of Infant Birthweight", Janice Bell, M.N., M.P.H., University of Washington Department of Health Services	EHS	Ongoing
B-052203-H	"A Retrospective Analysis of Deformation Plagiocephaly", Christy M. McKinney, M.P.H., University of Washington Department of Epidemiology	EHS	Ongoing
A-060203-H	"Failure of Nonoperative Management of Splenic Injuries: Causes and Consequences", Gregory J Jurkovich, M.D., Harborview Medical Center Department of Surgery	HSQA	Ongoing

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2003 Status
A-060503-H	"SARS Coronavirus EIA in Blood Samples", Dean Erdman, M.D., Centers for Disease Control & Prevention	EHS	Ongoing
B-060603-H	"Improving Investigations Conducted to Detect and Prevent Transmission of <i>Mycobacterium tuberculosis</i> in Foreign-born Communities in the US", Stefan Goldberg, M.D., Public Health-Seattle & King County	CFH	Ongoing
B-061603-S	"Pediatric Condition Falsification Database", Kenneth W Feldman, M.D., Children's Hospital & Regional Medical Center, Seattle, WA	CA	Ongoing
A-061703-S	"Prevalence, Patterns, and Impact of Mental Health Systems among Juvenile Detainees", Eric W. Trupin, Ph.D., University of Washington Department of Psychiatry & Behavioral Sciences	JRA	Ongoing
B-061703-S	"Recovery Measurement Prototype Project", Judy J. Hall, Ph.D., Department of Social & Health Services Mental Health Division	MHD	Ongoing
B-061803-S	"Clinical and Economic Impact of Pharmacist's Recommendations in Geropsychiatric Nursing Home Residents", Clarke St. Dennis, Ph.D., Washington State University College of Pharmacy	MHD	Ongoing
A-061903-H	"Risk Factors for Postpartum Suicide and Parasuicide", Melissa Schiff, M.D., M.P.H., Harborview Injury Prevention & Research Center	EHS	Ongoing
A-062003-H	"Assessment of the Risks and Benefits Associated with Receipt of STARHS Results", Gary M. Goldbaum, M.D., M.P.H., Public Health-Seattle & King County	CFH	Ongoing
A-062503-S	"Barriers to the Management of Child and Adolescent Depression", Laura P. Richardson, M.D., M.P.H., University of Washington Child Health Institute	MAA	Ongoing

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2003 Status
A-062603-H	“Geographic and Career Trajectories of Washington State’s J-1 Visa Waiver Program”, L. Gary Hart, Ph.D., University of Washington Department of Family Medicine	HSQA	Ongoing
A-062703-H	“TCE Exposure Assessment”, Jan C. Semenza, Ph.D., M.P.H., Portland State University	CFH	Ongoing
B-063003-S	“Peninsula Partnership--SAMHSA Cooperative Agreement”, Robert Bennett, M.A., Resource Development Associates, Lafayette, CA	MHD	Canceled



Washington State
Department of Social
& Health Services

Research and Data Analysis Division
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