

**Activity Report
Washington State Institutional Review Board
Fiscal Year 2004**

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 2004

August 2005

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 # 11.126

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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.

WASHINGTON STATE INSTITUTIONAL REVIEW BOARD A

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DSHS Human Research Review Section

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George Yeannakis, J.D.
Prisoner Representative

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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 2004

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 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 2004

Human Subject Protection Activities at the National Level

The Secretary of the Department of Health and Human Services approved a waiver of parts of 45 CFR 46, Subpart C, which was published in the Federal Register Vol 68, No. 119, Friday, June 20, 2003. Subpart C specifies special protections which must be in place in order to conduct biomedical and behavioral research involving prisoners as subjects. The waiver criteria apply only to epidemiologic research. To qualify for a waiver, the research must pose no more than minimal risk of harm and no more than inconvenience to subjects; prisoners cannot be the focus of the research.

The Office of Research Integrity within HHS noted that reports of research misconduct had increased for the fourth year in a row. Over 70% of misconduct reports during 2002 were generated by institutions of higher education. The total number of institutions reporting new allegations also increased. Research misconduct is defined as "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data" (42 CFR 50.102).

In a related development, in early 2004 the Office of Research Integrity issued proposed changes to current regulations regarding research misconduct. ORI proposes to expand the definition of misconduct, to include misconduct in review of research, whether grant applications or peer review of grant submissions and articles for publication. The proposed regulations would expand applicability to contractors, and would provide a broader definition of "data or results" to encompass all forms of scientific information--even oral presentations of research results. Fabrication, falsification, and plagiarism would be a "significant departure" from acceptable practices, instead of a "serious deviation", as stated in the current regulations. Level of intent would include recklessness. The public comment period for the proposed changes closed in mid-June 2004.

Bernard A. Schwetz, D.V.M., Ph.D., was appointed director of the Office for Human Research Protections (OHRP) on April 8, 2004. Dr. Schwetz had served as acting director of that office since February 2003. Dr. Schwetz plans to increase the presence of OHRP personnel for activities such as quality improvement within human subject protection programs. Dr. Schwetz previously served as the senior advisor for science at the Food and Drug Administration (FDA) and was a Distinguished Scientist at the University of Maryland, College Park, Maryland.

Financial conflict of interest continues to be a focus of human subjects protection at the national level. In December 2003, the Los Angeles Times reported that senior scientists and directors of Institutes within NIH have received large payments for consultation with pharmaceutical and biomedical companies whose products are monitored by the agency, speakers honorariums, and other incentives from private companies. NIH had revised its ethics system in 1995 to remove dollar limits on outside income, to permit employees to

receive company stock as compensation for outside activities, and to permit NIH employees to use work time to conduct outside activities. Publication of the Times article led to formation of a committee within NIH to evaluate conflict of interest. A Congressional subcommittee held hearings on this issue, and later expanded its investigation to NIH procedures used to review and approve outside employment. In May 2004, the Department of Health and Human Services issued new guidance for protecting research subjects from possible harm caused by financial conflicts of interest that may arise in research studies. The guidance applies to all human subjects research conducted or supported by HHS agencies or regulated by the Food and Drug Administration.

The Institute of Medicine Committee on Clinical Research Involving Children issued recommendations regarding preventive, diagnostic, treatment, and other clinical research involving interaction with children. The March 2004 report emphasizes that evaluation of risks to children should use as a comparison normal healthy children, rather than children who experience a similar disease or condition as the proposed research subjects. Researchers and IRBs should also focus on possible discomforts as they pertain to the age of children under study, and the duration of possible risks and discomforts in addition to its probability and magnitude. The committee thus rejected a relativistic assessment of risks to children, particularly when defining "minimal risk" to child subjects.

An Illinois Appellate Court ruled that the state health department must disclose cancer registry information in response to a request under the Freedom of Information Act. An expert on data anonymity testified at the Court hearings that she was able to re-identify records using readily available software and a laptop. The Court determined that the requested information would not allow for reidentification of individuals, and found it unlikely that persons lacking the expert's education and training would be able to re-link to other record sources and re-identify cancer patients. The June 9, 2004 decision in *The Southern Illinoisan v. Department of Health* has policymakers, researchers and data managers concerned that FOIA may trump health information privacy laws.

Human Subject Protection Activities at the Local Level

Board operating procedures were drafted over several months during FY 2004. Draft Review Board procedures were sent to key stakeholders in early March, were then finalized, adopted by the Review Board, and posted on the Review Section website in early April 2004. Section 6 of the operating procedures will be added to incorporate information regarding abuse reporting requirements; standards for translations of recruitment and consent documents; procedures for research recruitment of department clients or using confidential records, appropriate consent form language, and other issues. The Procedures Manual is a "work in progress", to which sections will be added on a regular basis and subsequently posted to the website.

In April 2004, the Federalwide Assurances for DSHS, L&I, and DOH were renewed with the Office of Human Research Protections for an additional three years. Any institution engaged in human subjects research (not otherwise exempt) that is conducted or supported by any agency of the U.S. Department of Health and Human Services (HHS), must have an OHRP-approved assurance of compliance with the HHS regulations for the protection of human subjects.

Review Section staff developed forms for study amendments and reporting adverse events or unanticipated problems that pose risks to subjects. After review and comment by Board members and researchers who conducted an informal "beta testing", the forms were finalized and posted on the Review Section website. In addition, a revised review presentation guide and protocol for presenting full committee proposals and study amendments was implemented during the summer of 2003. The presentation guide is a two-page "walk-through" for Primary Reviewers who present proposals to the full Review Board at a convened meeting. The guide covers all issues which must be considered during human subjects review, such as the regulatory requirements, assessment of risks and benefits, special protections, and requirements for informed consent. The revised guide provides a framework for the Chair for conducting the meetings, to ensure consistency, more focused discussion, and vote, if applicable, on these same issues.

Review Section staff attended a meeting of developers of the CITI web-based human subjects protection training program in Seattle in August 2003. The developers are also working on a training program for the responsible conduct of research. Staff reviewed proposed training modules for biomedical and social and behavioral research and provided suggestions for revision to the developers. The new CITI training course site was unveiled in the spring. Developers at the University of Miami added new features to make the site more attractive for the learners and friendlier for training coordinators. These new features include user self registration; user-determined usernames and passwords; immediate access at all times; modules from both biomedical and social/behavioral tracks. Quizzes are generated randomly and include feedback with the answers. A section regarding Conflict of Interest in Human Subjects Research was also incorporated. The Review Section Training Coordinator will now be able to download reports of training records.

The Review Section, with Review Board concurrence, implemented deidentification standards for datasets disclosed by DSHS, L&I, and DOH in October. DSHS, as a covered entity under HIPAA, already uses these standards. The DOH Center for Health Statistics developed deidentification standards for its databases several years ago. However, other department databases, such as the cancer registry and trauma registry, have no written procedures or standardized method researchers must follow when they are required to deidentify datasets at the end of their research. The proposed standards would only apply to records disclosed by the respective agencies for research purposes.

In March 2004, Review Section staff met with University of Washington School of Social Work faculty and researchers. This was the first in a series of outreach activities targeting institutions and researchers which submit proposals to the WSIRB. The presentation focused primarily on the cooperative review agreement between DSHS and the University of Washington; WSIRB jurisdiction; timelines for review and approval; the recent quality improvement initiative; the pre-review process for full committee reviews. As a number of graduate-level social work students submit proposals to the WSIRB in which they request disclosure of personally identifiable records or propose interaction with DSHS clients, the presentation also focused on issues that arise during review of student research. Faculty were informed that many public use datasets would be useful for student research, particularly if a research project is required as a class assignment, as opposed to

dissertation or thesis research. The issue of departmental employees conducting research with DSHS records or clients in order to meet educational requirements (e.g., personal reasons) was also discussed. Such research requires review and approval by the WSIRB, if human subjects are involved.

In June 2004, Review Section staff conducted a workshop on human subjects protection and policies and procedures of the WSIRB at Fircrest School in Shoreline. The training was intended to raise awareness of the need for human subjects review if research would be conducted within the DSHS Division of Developmental Disabilities. Training attendees were primarily clinical, social work, and supervisory staff within the Division. Similar workshops will take place within other DSHS program areas as well as other research institutions and state agencies on a regular basis.

In April 2004, Cindy Bouillon-Jensen marked 10 years of service on the Review Board, becoming the third Distinguished Member. Ms. Bouillon-Jensen will continue to serve on the Review Board as a non-scientist member.

Many local research institutions are implementing electronic procedures for conducting human subjects reviews, such as electronic submission of proposals via email or web-based systems, use of laptops during committee meetings, and more sophisticated systems for generating correspondence to investigators and tracking protocols. The Review Section is exploring options for replacing its database to a more flexible, comprehensive system, or potentially a secure web-based system for application submission and review.

A regional IRB conference took place in Bellevue on October 27, 2003. The event was sponsored by the University of Washington. Review Section staff presented "Privacy and Confidentiality in Research". The Northwest Regional IRB Conference: The Basics and Beyond took place in Portland May 3-4, 2004. The conference was sponsored by the Applied Research Ethics National Associate (ARENA) and several Portland-area research institutions. This regional conference brought in nationally recognized speakers to discuss basic and advanced emerging issues in human research protections.

IX. REVIEW VOLUME AND TRENDS

Figure 1 provides three measures of Review Board activity during the past 22 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 41% during the most recent ten-year period, from 217 in 1995 to 306 in 2004.

Figure 1
Review Volume
Fiscal Years 1983 - 2004

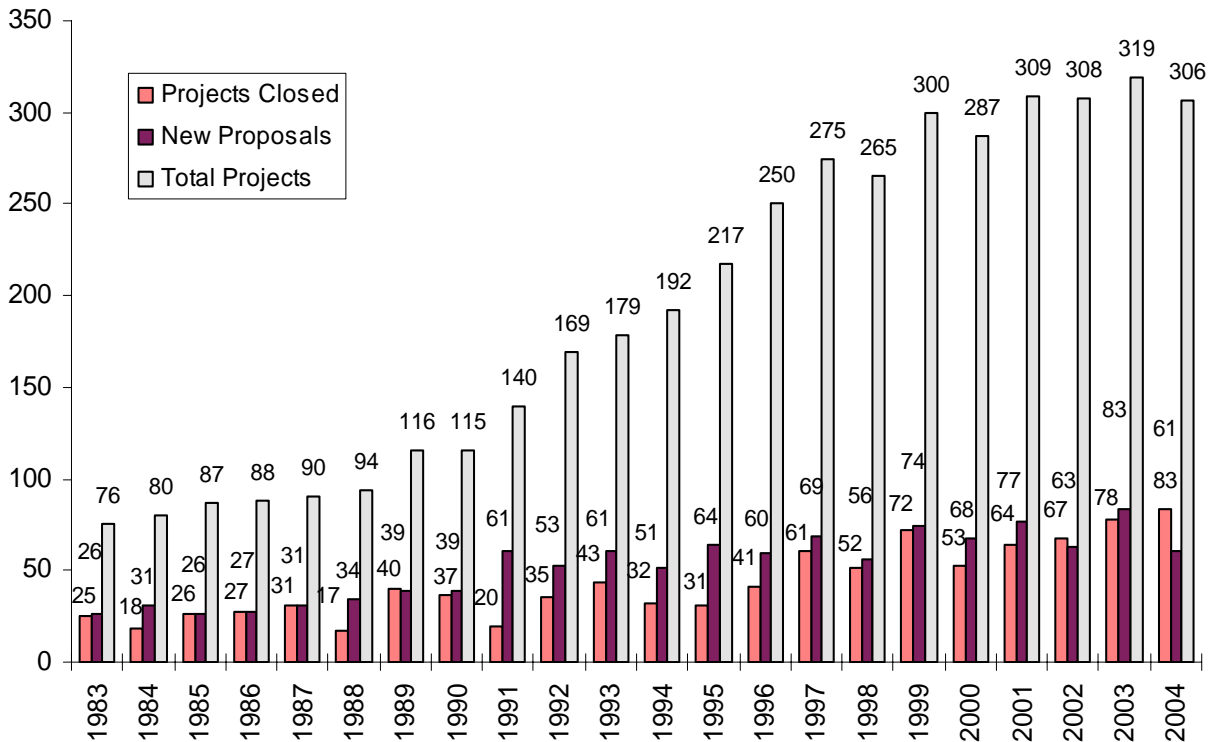


Figure 2 shows the distribution of new research proposals by agency and program for Fiscal Year 2004. The Department of Social and Health Services accounted for almost 60% of the new proposals reviewed during FY 2004. Children's Administration and Medical Assistance led DSHS program areas in the amount of research reviewed, each accounting for 15% of new proposals. About 38% of the new proposals reviewed were in the jurisdiction of the Department of Health, with 19% in Epidemiology and Health Statistics and 13% in Community and Family Health. Two percent of the proposals reviewed were in the jurisdiction of the Department of Labor and Industries.

Figure 2
 Research Proposals by Agency Program
 FY 2004
 N=61

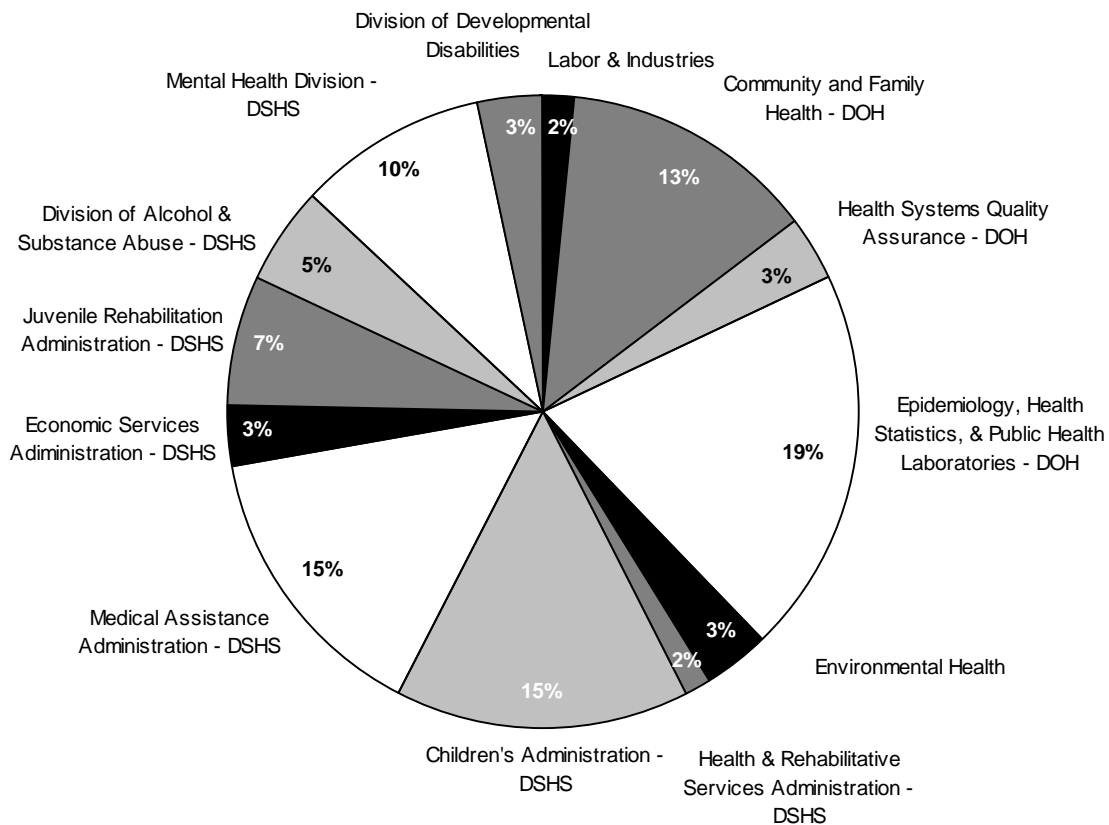
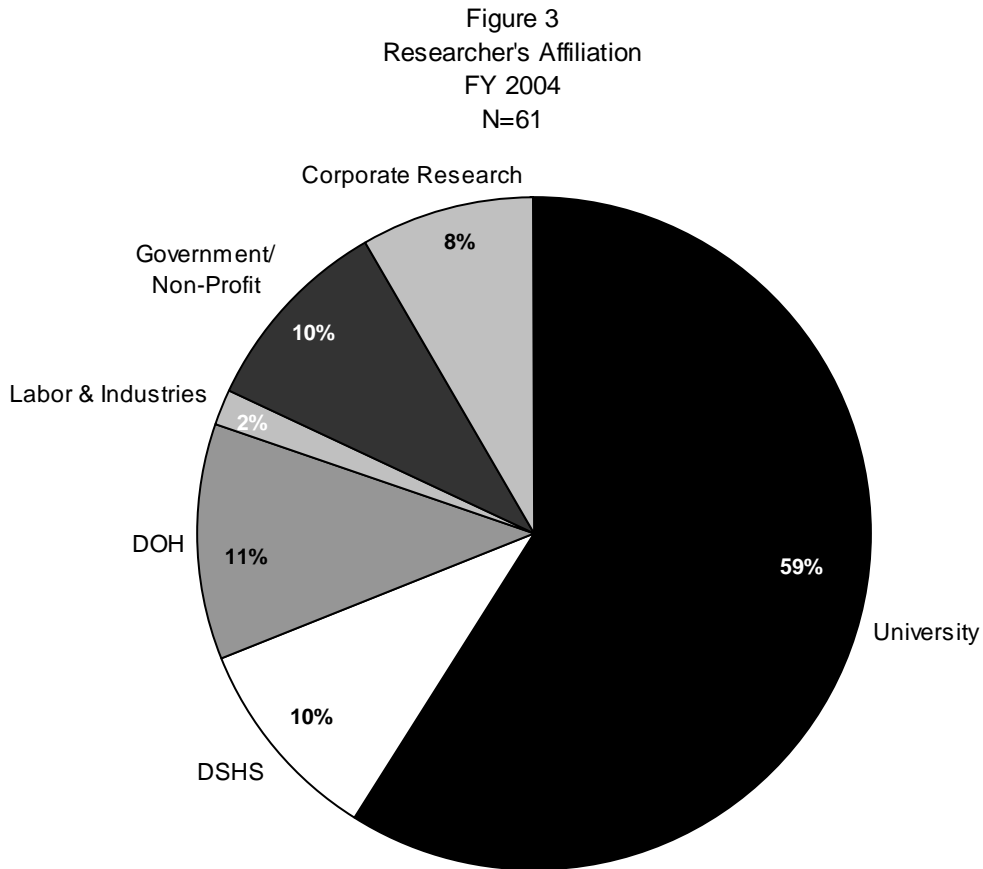


Figure 3 shows the organizational affiliation of the principal investigators for new research proposals received during Fiscal Year 2004. Almost 60% of the principal investigators were university-based, with the University of Washington accounting for the large majority.



X. RESEARCH PROPOSALS: FISCAL YEAR 2004

New research proposals reviewed by the Board during Fiscal Year 2004 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 2004.

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.

Within DSHS program areas, research involving Medicaid recipients continues to be a major focus. Research reviewed during FY 04 covered a variety of topics, including quality of care (B-071603-S, A-102403-S); psychotropic medication use among children (A-091003-S); dental care for mothers and their pre-school children (B-091503-S); the health of women with developmental disabilities (A-121803-S); Medicaid capitation and cost-shifting (B-121903-S); and prostate and colorectal cancer screening (A-031204-S). An equal proportion of proposals involved Children's Administration programs and clients. For example, proposals reviewed by the WSIRB focused on evaluations of programs targeting drug-endangered children (B-090503-S); family reunification (A-110703-S); and a local parenting project (A-021704). Other DSHS-related research involved juvenile offenders (B-011304-S, B-040604-S), and patients (B-091703-S, B-092203-S, B-042104-S) and staff (B-030304-S) at Western State Hospital.

The majority of proposals reviewed within the jurisdiction of DOH were in Epidemiology and Health Statistics. As this program area of DOH maintains several public health datasets, researchers frequently request disclosure of personally identifiable records for their research. Research reviewed in this program area during FY 04 involved environmental causes of chronic disease (B-072203-H); maternal and child health (B-073103-H, A-012604-H, B-020504-H); domestic violence (A-101003-H); and drug resistant (C-012704-H) and emerging (C-020204-H) infections. Research in the jurisdiction of DOH also frequently involves contact with human subjects; some proposals involve survey or focus group procedures (B-102903-H, A-012904-H, while other research may also involve blood draws and other biological specimen collection (A-121703-H, B-062304-H, A-031104-H).

Research within the Department of Labor and Industries decreased somewhat in FY 04, although many studies reviewed in previous years are still ongoing.

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 2004**

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)

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
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
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Status

Ongoing	Project pending final approval, or approved and continuing
Canceled	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 Code	Proposal Title and Principal Investigator	Program	July 1, 2004 Status
A-070303-L	"Characterization of Ventilation Effectiveness in Radiator Repair Shops", Carolyn Whitaker, M.S., L&I/SHARP	SHARP	Canceled
B-071603-S	"Medicaid MCO's and Quality of Asthma Care", Dimitri Christakis, M.D., M.P.H., University of Washington Child Health Institute	MAA	Ongoing
B-072203-H	"Investigating Environmental Causes of Chronic Disease", Dan Wartenberg, Ph.D., Environmental & Occupational Health Sciences Institute, Piscataway, NJ	EHS	Ongoing
A-073003-H	"STARHS HIV Incidence Study", Susan E. Buskin, Ph.D., M.P.H., Public Health-Seattle & King County	CFH	Ongoing
B-073103-H	"Race, Ethnicity, and Quality of Care for Newborns", Laurence Baker, Ph.D., Stanford University	EHS	Ongoing
B-090403-H	"Co-Sleeping and Sudden Infant Death in Washington", Teresa Vollan, University of Washington Department of Epidemiology	CFH	Canceled
B-090503-S	"Evaluation of the Collaborative Community Response to Drug Endangered Children", Sandra J. Altshuler, Ph.D., Eastern Washington University School of Social Work	CA	Ongoing
A-091003-S	"Psychotropic Prescription Rates for Juveniles in Washington State", Jon M. McClellan, M.D., DSHS Child Study & Treatment Center	MAA	Ongoing
A-091203-H	"Changes in Hospitalization Rate and Hospital Cost of Traffic-Related Injuries", Bahman S. Roudsari, M.D., M.P.H., Harborview Injury Prevention & Research Center	HSQA	Canceled
B-091503-S	"Linking Mother and Child Access to Dental Care", David Grembowski, Ph.D., University of Washington Dental Public Health Sciences	MAA	Ongoing
B-091703-S	"Contradictions of Re-Institutionalization in Forensic Psychiatry", Jen-Yu Chou, M.D., University of	MHD	Ongoing

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2004 Status
	Washington Department of Anthropology		
B-092203-S	"Factors Associated with Level of Violence among Individuals Found Not Guilty by Reason of Insanity", Mark Koenen, M.D., University of Washington Department of Psychiatry & Behavioral Sciences	MHD	Ongoing
A-101003-H	"Prevention of IPV: Victim Support Team Evaluation", Mary A. Kernic, Ph.D., University of Washington Department of Epidemiology	EHS	Ongoing
A-102403-S	"Quality of Health Care for Children of Non-English Speaking Parents", Adam L. Cohen, M.D., M.P.H., University of Washington Child Health Institute	MAA	Ongoing
B-102903-H	"Healthy Youth Survey 2004", Lillian Bensley, Ph.D., DOH Office of Epidemiology	EHS	Ongoing
B-110603-S	"Archival Discriminators of Sexual Sadism among Civilly Committed Sex Offenders", Henry J. Richards, Ph.D., University of Washington Department of Psychiatry & Behavioral Sciences	HRS	Ongoing
A-110703-S	"An Evaluation of Two Family Reunification and Stabilization Programs", Diana J. English, Ph.D., DSHS Office of Children's Administration Research	CA	Ongoing
A-120103-H	"Survey of Endoscopic Capacity at the State Level", Juliet Van Eenwyk, Ph.D., DOH Office of Epidemiology	EHS	Ongoing
B-121503-S	"The Role of Music Therapy in the Treatment of Adolescents Who Have Experienced Trauma", Jennifer G. Wyatt, M.M., Seattle Children's Home	CA	Ongoing
A-121703-H	"Well Water Quality and Infant Health Study", James Van Derslice, Ph.D., DOH Office of Environmental Health Assessments	EHP	Ongoing
A-121803-S	"Drug Use and Fracture Rate in Women with Developmental Disabilities who Received Fee-for-Service Medicaid in Washington State during 2002", Kathleen C. Watson, Ph.D., R.N., University of Washington School of Nursing	MAA	Ongoing

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B-121903-S	"Medicaid Capitation: Cost Shifting and Multisystem Use", Joseph P. Morrissey, Ph.D., University of North Carolina Sheps Center for Health Services Research	MAA	Ongoing
A-011204-S	"SEARCH for Diabetes in Youth of the Puget Sound", Lenna Liu, M.D., M.P.H., University of Washington Child Health Institute	MAA	Canceled
B-011304-S	"Prevalence, Patterns, and Impact of Mental Health Symptoms among Juvenile Detainees", Eric W. Trupin, Ph.D., University of Washington Department of Psychiatry & Behavioral Sciences	JRA	Ongoing
A-011404-H	"Trichloroethylene Exposure Assessment", Jan C. Semenza, Ph.D., M.P.H., Portland State University	CFH	Canceled
A-012604-H	"Extent of Maternal Morbidity in a Managed Care Setting", Mark C. Hornbrook, Ph.D., Kaiser Permanente Center for Health Research, Portland, OR	EHS	Ongoing
A-012704-S	"Solving the Problem of Attachment in Foster Children", Pamela R. Klem, M. Ed., Nova Southeastern University	CA	Canceled
C-012704-H	"Interviews of Patients Infected with Bacterial Enteric Pathogens with an Unusual Resistance Pattern", Fred Angulo, D.V.M., Ph.D., Centers for Disease Control and Prevention, Atlanta, GA	EHS	Ongoing
A-012804-S	"Parent-Child Assistance Program", Therese M. Grant, Ph.D., University of Washington Department of Psychiatry & Behavioral Sciences	DASA	Ongoing
B-012804-H	"The Environmental Determinants of Diabetes in Youth (TEDDY) Study", William A. Hagopian, M.D., Ph.D., Pacific Northwest Research Institute, Seattle, WA	CFH	Canceled
A-012904-H	"Growing Up Healthy", Riley M. Peters, Ph.D., DOH Maternal and Child Health	CFH	Ongoing
B-012904-S	"Evaluation of a Pharmacy Intervention in Geriatric	MHD	Ongoing

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	Assisted Living Facility Residents”, Paul Peterson, Ph.D., Washington Institute for Mental Illness Research & Training		
A-013004-S	“Washington State Screening, Brief Intervention, Referral and Treatment Evaluation Project”, Sharon Estee, Ph.D., DSHS Research & Data Analysis	DASA	Ongoing
B-013004-S	“The Meaning to Low Socioeconomic Parents of Keeping Children Safe”, Linda C. Gwinn, R.N., Washington State University-Vancouver	ESA	Ongoing
A-020204-S	“Training, Development, and Implementation of a Forensic Interviewing Protocol for CPS Workers”, Brooke Sandoval, M.S.W., Nova Southeastern University	CA	Canceled
B-020204-S	“Reclaiming Futures Local Evaluation for King County Superior Court”, Peter M. Selby, Ph.D., TriWest Group, Seattle, WA	DASA	Ongoing
C-020404-H	“RT-PCR Assays to Detect SARS Coronavirus in Respiratory Specimens”, Dean Erdman, Dr.P.H., Centers for Disease Control and Prevention, Atlanta, GA	EHS	Ongoing
B-020504-H	“Changes in the Spatial Pattern of Pre-eclampsia in Washington State: 1990-2000”, Carole Butler, M.P.H., University of Washington Department of Epidemiology	EHS	Ongoing
A-021004-H	“Cohort Cancer Registry Follow-up Study”, Meir Stampfer, M.D., Dr.P.H., Brigham and Women’s Hospital, Boston, MA	CFH	Ongoing
A-021104-S	“Effects of Father Involvement on Child Mental Health”, Mary A. Kernic, Ph.D., University of Washington Department of Epidemiology	CA	Ongoing
B-021104-S	“Demonstration and Evaluation of Centralized Medical Support Enforcement”, John Tapogna, M.P.P., ECONorthwest, Portland, OR	ESA	Ongoing
B-021304-H	“Socioeconomic and Demographic Disparities in Treatment of Colorectal Cancers: An Update”,	EHS	Ongoing

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	Juliet Van Eenwyk, Ph.D., DOH Office of Epidemiology		
A-021704-S	"Vancouver Parent Mentoring Project", Maureen O. Marcenko, Ph.D., University of Washington School of Social Work	CA	Ongoing
B-030304-S	"Understanding the Experiences of Nursing Staff Returning to Work after an Assault", Steven Baltz, R.N., University of Washington School of Nursing	MHD	Ongoing
A-031004-S	"Transracial and Gay or Lesbian Placements of Children in the Child Welfare System", Amy Willard, Walla Walla College	CA	Ongoing
A-031104-H	"Overexposure to Mercury in Members of the Asian/Pacific Islander Community", Koenraad Mariën, Ph.D., DOH Office of Environmental Health Assessments	EHP	Ongoing
A-031204-S	"Prostate and Colorectal Cancer Screening", Jeffrey Harris, M.D., M.P.H., University of Washington Health Promotion Research Center	MAA	Ongoing
B-032504-S	"Behavioral Outcomes between Behavior Modification and Positive Behavior Support Programs", Christine Rice, Central Washington University	DDD	Ongoing
B-040604-S	"Functional Family Therapy in the Treatment of Juvenile Sex Offenders", Thomas L. Sexton, Ph.D., Indiana University School of Education	JRA	Ongoing
A-041504-S	"CPS Response to Drug Abusing Single Mothers", Cynthia Matthiesen, M.S.W., University of Washington School of Social Work	CA	Ongoing
A-041604-S	"Charges for Trauma Care", Frederick P. Rivara, M.D., M.P.H., University of Washington Child Health Institute	MAA	Ongoing
B-042104-S	"Predictors of Voluntary and Involuntary Psychiatric Admissions in Minors", Frances Lexcen, Ph.D., DSHS Child Study & Treatment Center	MHD	Ongoing

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A-042204-S	"Modeling the Role of Consumer and Family Choice in Developmental Disabilities Services", Susan Neely-Barnes, M.S.W., University of Washington School of Social Work	DDD	Ongoing
B-042904-S	"Fast Track: Multisite Prevention of Conduct Disorders", Robert J. McMahon, Ph.D., University of Washington Department of Psychology	JRA	Ongoing
B-043004-H	"Data Linkage to Evaluate Washington State Diabetes Collaborative", Amira El-Bastawissi, Ph.D., DOH Community Wellness and Prevention	CFH	Ongoing
A-050304-H	"Stroke and Blunt Cervical Vascular Injury", Marjorie Wang, M.D., University of Washington Robert Wood Johnson Clinical Scholars Program	EHS	Ongoing
B-061704-S	"Criminal Pre-Trial Neuropsychological Evaluations", Audrey Mattson, Ph.D., Western State Hospital	MHD	Ongoing
A-061804-H	"Reasons for Non-Use of Public Benefits by Eligible Families", Deborah Zeidenberg, M.P.A., Office of Financial Management	EHS	Ongoing
A-062104-H	"Interfacility Transfers in the Central Region Trauma Registry", Danelle Wallace, M.P.H., Harborview Injury Prevention & Research Center	HSQA	Ongoing
B-062104-S	"Evaluation of the Effects of Substance Abuse Treatment for General-Assistance Unemployable Clients", Thomas Wickizer, Ph.D., Independent Consultant	DASA	Ongoing
B-062304-H	"The Environmental Determinants of Diabetes in Youth (TEDDY) Study", William A. Hagopian, M.D., Ph.D., Pacific Northwest Research Institute, Seattle, WA	CFH	Ongoing



Washington State
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Research and Data Analysis Division
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