

Activity Report
DSHS/DOH
Human Research Review Board
Fiscal Year 2001

ACTIVITY REPORT

DEPARTMENT OF SOCIAL AND HEALTH SERVICES DEPARTMENT OF HEALTH

HUMAN RESEARCH REVIEW BOARD

Fiscal Year 2001

January 2002

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 # 11.102

DEPARTMENT OF SOCIAL AND HEALTH SERVICES

Dennis Braddock, Secretary

MANAGEMENT SERVICES ADMINISTRATION

Kennith Harden, Assistant Secretary

RESEARCH AND DATA ANALYSIS

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 DSHS/DOH Human Research 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 and the Department of Health.

DEPARTMENT OF SOCIAL AND HEALTH SERVICES - DEPARTMENT OF HEALTH HUMAN RESEARCH REVIEW BOARD A

Executive Secretary

Michael A. Garrick, Ph.D.

Coordinator

DSHS Human Research Review Section

Associate Executive Secretary

Margaret Frederick, M.P.H.

Review Coordinator

DSHS Human Research Review Section

Members

Nancy Anderson, M.D., M.P.H.

Medical Epidemiologist

DSHS Medical Assistance Administration

Carol Brandford, M.S.W.

Research Manager

DSHS Children's Administration Research

Pat deHart, Sc.D.

Epidemiologist

DOH Immunization Project

Marcia Goldoft, M.D., M.P.H.

Physician Epidemiologist

DOH Communicable Disease Epidemiology

Martha Holliday, M.P.H.

Project Director

NW Portland Area Indian Health Board

Daniel R. Kivlahan, Ph.D.

Director, CESATE

VA Puget Sound Health Care System

Chairperson

Sharon L. Estee, Ph.D.

Research Supervisor

DSHS Research and Data Analysis

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

Dennis McBride, Ph.D.

Senior Research Associate

The Washington Institute, Western Branch

Danna Moore, Ph.D.

Research Coordinator

WSU Social and Economic Sciences Research Center

Robert D. Mootz, D.C.

Associate Medical Director for Chiropractic

Department of Labor & Industries

James VanDerslice, Ph.D.

Environmental Epidemiologist

DOH Environmental Health Programs

George Yeannakis, J.D.

Prisoner Representative

DEPARTMENT OF SOCIAL AND HEALTH SERVICES - DEPARTMENT OF HEALTH HUMAN RESEARCH REVIEW BOARD B

Executive Secretary

Michael A. Garrick, Ph.D.

Coordinator

DSHS Human Research Review Section

Associate Executive Secretary

Margaret Frederick, M.P.H.

Review Coordinator

DSHS Human Research Review Section

<u>Members</u>

Andrew Borland, M.D.

Psychiatrist

Western State Hospital

Cindy Bouillon-Jensen, M.A. Community Representative

Kevin Campbell, Dr.P.H. Research Investigator

DSHS Alcohol and Substance Abuse

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

Western State Hospital

Robert M. Fineman, M.D., Ph.D.

Medical Consultant

DOH Maternal & Child Health

Thomas James, Ph.D.

Lead Psychologist

Rainier School

Victoria Lombardini-Kerns, B.S.N.

Public Health Nurse

Public Health Seattle-King County

Chairperson

Lillian Southwick Bensley, Ph.D.

Epidemiologist

DOH Office of Epidemiology

Robert A. Short, Ph.D. Research Associate

Washington Institute, Eastern Branch

John Steiger, Ph.D. Senior Forecaster

Caseload Forecast Council

Hanne Thiede, D.V.M., M.P.H.

Epidemiologist

Seattle-King County Dept of Public Health

George Yeannakis, J.D.

Prisoner Representative

Alternates:

Nancy Anderson, M.D., M.P.H.

Medical Epidemiologist

DSHS Medical Assistance Administration

Marcia Goldoft, M.D., M.P.H.

Physician Epidemiologist

DOH Communicable Disease Epidemiology

Jon McClellan, M.D.

Medical Director

Child Study and Treatment Center

TABLE OF CONTENTS

EXEC	CUTIVE SUMMARY	Xi
l.	PURPOSE	1
II.	AUTHORITY	1
III.	ACTIVITIES SUBJECT TO BOARD REVIEW	_2
IV.	ADMINISTRATION	.2
V.	REVIEW BOARD FUNCTIONS	3
VI.	REVIEW BOARD MEMBERSHIP	.3
VII.	REVIEW PROCESS	.3
VIII.	MAJOR ACTIVITIES: FISCAL YEAR 2001	4
IX.	REVIEW VOLUME AND TRENDS	.8
X.	RESEARCH PROPOSALS: FISCAL YEAR 2001	.10
XI.	PROJECT LOG	.13

EXECUTIVE SUMMARY

THIS REPORT PROVIDES AN OVERVIEW OF THE DSHS/DOH HUMAN RESEARCH REVIEW BOARD. IT SUMMARIZES THE BOARD'S AUTHORITY AND FUNCTIONS, OUTLINES THE HUMAN RESEARCH REVIEW PROCESS, AND DESCRIBES MAJOR ACTIVITIES DURING FISCAL YEAR 2001. IT ALSO INCLUDES A LOG OF ALL RESEARCH PROJECTS WHICH WERE REVIEWED DURING THIS PERIOD.

Under a Federalwide Assurance with the Department of Health and Human Services, the DSHS/DOH Human Research Review Board must review and approve all research (except exempted categories) sponsored by the Department of Social and Health Services (DSHS) or the Department of Health (DOH), conducted by or under the direction of any employee of agent of DSHS or DOH, using any DSHS or DOH property or facility, or using any non-public information held by DSHS or DOH 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 DSHS/DOH Human Research Review Board is comprised of professionals working both within and outside DSHS and DOH. Each Board also has at least one community representative. 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 *Guide to DSHS/DOH Policy on Protection of Human Research Subjects* (revised July 1, 1998) and the departments' Research Application Kit, may be obtained by contacting the Human Research Review Section, Mail Stop: 45205, Olympia, Wa. You may contact the Review Section at (360) 902-8075 or by email at: hrrb@dshs.wa.gov. These documents and additional information are also available on the Section's website: http://www-app2.wa.gov/dshs/rda/hrrb/human_research.htm.

ACTIVITY REPORT

Department of Social and Health Services Department of Health

Human Research Review Board

Fiscal Year 2001

I. PURPOSE

The Department of Social and Health Services (DSHS) and the Department of Health (DOH) 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 and DOH have fulfilled this responsibility by establishing a formal policy for the protection of human subjects, and by maintaining a standing Institutional Review Board (IRB) which operates under the auspices of a Federalwide Assurance (FWA) with the federal Department of Health and Human Services. The departments' IRB is the DSHS/DOH Human Research Review Board.

The DSHS/DOH Human Research 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 regulation (45 CFR 46) 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, and DOH Administrative Policy 03.001, 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 and procedures are described more fully in the *Guide to DSHS/DOH Policy on Protection of Human Research Subjects*, revised July 1, 1998, available by contacting the Human Research Review Section at (360) 902-8075 or at our website: http://www-app2.wa.gov/dshs/rda/hrrb/human_research.htm.

III. ACTIVITIES SUBJECT TO BOARD REVIEW

Except for research activities specifically exempted in the *Guide to DSHS/DOH Policy*..., Section XI, the departments' human research review policy applies to all research and related activities that are (i) sponsored by DSHS or DOH, (ii) conducted by an employee or agent of DSHS or DOH, (iii) which use any DSHS or DOH property or facility, or (iv) which involve the use of DSHS or DOH non-public information to identify or contact human research subjects or prospective subjects. The policy applies to research and related activities contracted by DSHS and DOH 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 *Guide to DSHS/DOH Policy...*, Sections IV and XI. This document, however, may not always provide enough information to distinguish between research and related activities which are subject to review, and administrative data collection or program monitoring activities which are not subject to review. To meet this need, *Jurisdictional Guidelines* have been developed to assist researchers and program managers in determining the boundaries of Review Board jurisdiction. In addition, Guidelines developed by the Centers for Disease Control and Prevention draw distinctions between public health research and public health practice. These two sets of guidelines are available on request from the Human Research Review Section.

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 DSHS/DOH human research review policy. The Section Coordinator and Review Coordinator provide liaison between DSHS and DOH 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 Kits are available from the Review Section and 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 DSHS/DOH Human Research Review Board is to protect the interests of individuals participating in research within the departments' jurisdiction. An important secondary function is to provide DSHS/DOH management with the necessary expertise to determine whether proposed research is valid, worthwhile, and in compliance with federal and state statutes and regulations. DSHS and DOH 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 and DOH, 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 are employed full time 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 vi.

VII. REVIEW PROCESS

Investigators wishing to conduct human subjects research which falls under DSHS/DOH 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 full Review Boards for consideration at a regularly scheduled meeting, or are reviewed by two or more Board members through the expedited process (See *Guide to DSHS/DOH Policy...*, Section X for activities that are eligible for expedited review).

Copies of proposals requiring full Board review are sent to all members two weeks prior to the meeting. One member is asked to be the "primary reviewer" and to present the proposal to the Board at the meeting. The primary reviewer may contact the researcher before the meeting to discuss potential concerns or to obtain additional information. 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 *Guide to DSHS/DOH Policy...*, Section VII. The Board also uses the more detailed *Standard Review Criteria*, published by the Review Section and included in the Research Application Kit, as a checklist to promote thorough and consistent reviews of all research proposals.

Following presentation of the proposal and discussion of any concerns, the primary reviewer is asked for a disposition recommendation. 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 revisions or clarifications, hold the proposal in abeyance 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 or DOH 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 2001

Human Subject Protection Activities at the Federal Level

Continuing a pattern that began in 1999, several prominent research institutions were sanctioned or temporarily shutdown for apparent breaches in human subjects protection, including the death of a healthy volunteer at a medical center affiliated with Johns Hopkins University. Media accounts of other problems of human subjects protection and the IRB process increased the call for stricter standards for IRBs and greater scrutiny of research and researchers. At the federal level, these concerns lead to several developments to address the perceived shortcomings of IRBs and the current system of protections:

The National Institutes of Health (NIH) announced that researchers submitting grant proposals, non-competing renewal applications, and annual reports for federally-funded research contracts must provide proof of training in human subjects protections and the ethical framework under which research may be conducted. The requirement took effect October 1, 2000, and applies to all personnel responsible for study design and conduct of research activities. NIH did not specify training requirements nor acceptable training programs; the requirement will be superceded by the DHHS Office of Research Integrity's pending requirements for training in the responsible conduct of research.

A Congressional Representative from Colorado introduced a bill ("Human Research Subject Protection Act of 2000") which would extend the protections of 45 CFR 46 (the Common Rule) to *all* research in the United States, regardless of funding source or location. The bill also would require ongoing education of IRB members and accreditation of IRBs. While the bill failed to pass, it is an example of a trend at the national level to increase oversight of IRB's and to strengthen the role and function of IRB's within their home institutions.

The Office of Research Integrity in the Department of Health and Human Services issued new requirements for training in the "responsible conduct of research (RCR)". The policy has broad application, in that it applies to "all staff who conduct research or who receive research training" with Public Health Service funds and all persons who are involved with PHS-supported research. The policy outlines six primary objectives of the research training and lists ten core elements of the required training (one of which is human subjects protections). The training requirement is another response to the death of a participant in a gene transfer trial at the University of Pennsylvania in 1999 and the recent suspension of research activities in several institutions. The RCR policy was to have taken effect in December 2000, but implementation of the requirement was postponed by the new federal administration.

Proposed revisions to Subpart B of 45 CFR 46, Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research, were published in the Federal Register and the public comment period was extended into late 2001. Revisions to this Subpart would facilitate inclusion of pregnant women in research by establishing the woman as the sole decision-maker regarding her own research participation. These revisions were a result of reports and recommendations issued since 1994 by the Institute of Medicine, the Presidential Advisory Council on HIV/AIDS, and the National Task Force on AIDS Drug Development, in which these bodies indicated that a lack of paternal consent should not exclude pregnant women from federally-funded research. Research directed solely at the fetus, however, would continue to require paternal as well as maternal consent.

The National Bioethics Advisory Commission (NBAC) issued a report on "Ethical And Policy Issues in Research Involving Human Participants". The report outlines several regulatory, structural, and local areas in which the current system of oversight of human subjects research requires modification. A key element of the report is a recommendation for Congress to pass legislation to broaden the scope of human subjects protection to cover all human subjects research, regardless of funding source. NBAC also recommends creation of a new federal agency responsible for the oversight of all human subjects research. The draft report can be found at http://bioethics.gov/human/humanpdf toc.html.

In other areas of human subjects protection and the ethical conduct of research, the World Medical Association (WMA) approved revisions to the Declaration of Helsinki in October 2000. The Declaration was revised to address the rapid changes in medical research. Concerned about the possibility of exploitation of poorer nations and their citizens in drug trials and other biomedical research, the WMA advocates that "every patient entered in a research project be assured of the best proven prophylactic, diagnostic, or therapeutic methods identified by the research". A copy of the updated Declaration of Helsinki is available on the Internet at http://www.wma.net/e/policy/17-c e.html.

The Health Insurance Portability and Accountability Act (HIPAA) privacy rules were published on April 16, 2001. As part of these new federal regulations, all agencies which provide health care, administer health plans, or operate as a health care clearinghouse are required to implement comprehensive policies and procedures for protecting the privacy of health care information by April 2003. DSHS and DOH established workgroups and executive committees to identify health information which is subject to the new privacy regulations and to plan how to implement the regulations. The privacy regulations include provisions for use and disclosure of protected health information for research purposes. The privacy regulations are consistent with federal human subjects protection regulations which allow use and disclosure of protected health information for research purposes without consent only with institutional review board (IRB) approval and under stringent procedures based on current regulations and state statutes.

Review Section Staff Activities

In response to initiatives at the federal level, the DSHS Human Research Review Section focused considerable effort this year on meeting federal requirements for the assurance process and research misconduct, developing on-line resources for researchers who wish to submit applications to the DSHS/DOH Review Board, and identifying and improving human subjects training resources for researchers and IRB members.

In December 2000, the federal Office of Human Research Protections (OHRP) revised procedures for establishing assurances with federal regulations for the protection of human research subjects. In response, DSHS and DOH each established new Federalwide Assurance (FWA) that replaced the dual-agency Multiple Project Assurance (MPA) which expired on December 31, 2000. Like the MPA, the FWA applies to all research involving human subjects that is in DSHS or DOH jurisdiction, regardless of the source of funding. All DSHS and DOH signatories to the FWA, including institutional officials, IRB staff, and the Review Board Chairs, were required to complete an on-line OHRP training module in human subjects protection. The Department of Labor and Industries, the Southwest Washington Health District, and Public Health - Seattle and King County, also established FWAs and designated the DSHS/DOH Human Research Review Board as an IRB for their respective agencies.

Working with a contractor, the Review Section developed a formal DSHS policy on research misconduct. As a requirement for the receipt of federal research funds, DSHS has had an interim policy on research misconduct since 1995, and has filed annual reports to the federal Office of Research Integrity. The formal policy defines the policies and procedures for conducting an inquiry, and if necessary an investigation, into allegations of research misconduct by DSHS employees. Research misconduct means 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 of judgments of data. (DSHS Administrative Policy 12.06, Research Misconduct, became effective on September 1, 2001.)

The Review Section's website came online in March 2001. The website contains research application forms, progress reports forms, and the *Guide to DSHS/DOH Policy on Protection of Human Research Subjects*. The website also contains links to other IRBs and to various state and federal laws and regulations pertaining to human subjects research, the Review Section's Activity Reports, published annually, and other pertinent information. The website is found at: http://www-app2.wa.gov/dshs/rda/HRRB/human_research.htm.

New Board members attended a half-day training at the Fred Hutchinson Cancer Research Center (FHCRC) in October 2000. Review Section staff presented a module on privacy and confidentiality issues in research. The training was a collaboration between DSHS/DOH, the FHCRC, the University of Washington, Children's Hospital and Regional Medical Center, Western IRB, and other local research institutions. Review Section staff also identified on-line training resources which meet the new federal requirements for researchers submitting applications for federal research funds to document appropriate training in the protection of human research subjects.

IX. REVIEW VOLUME AND TRENDS

Figure 1 provides three measures of Review Board activity during the past 19 years. The number of new research proposals submitted for review increased slowly during the period between 1983 to 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 83% during the ten-year period from 1992 to 2001, from 169 in 1992 to 309 in 2001.

Figure 1 Review Volume Fiscal Years 1983 - 2001

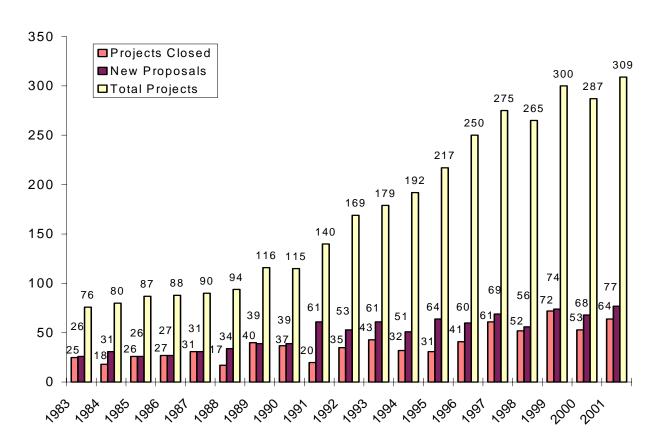


Figure 2 shows the distribution of new research proposals by agency and program for Fiscal Year 2001. Twenty-two percent of all new proposals were for research involving Epidemiology and Health Statistics in DOH, which reflects a 3% increase from Fiscal Year 2000. Fifteen percent of all proposals reviewed this year were related to programs in DOH Community and Family Health. Four DSHS programs also accounted for a significant percentage of proposals reviewed: Children's Administration (16%); Medical Assistance Administration (13%); Mental Health Division (7%); and Economic Services Administration (7%).

Figure 2
Research Proposals by Agency Program
FY 2001
N=77

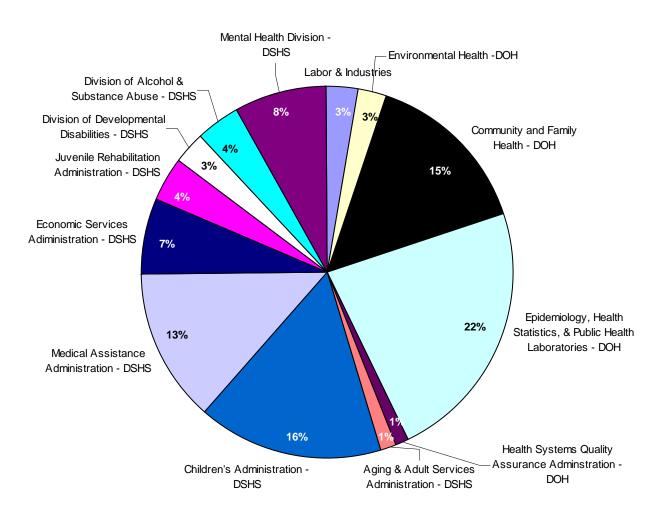
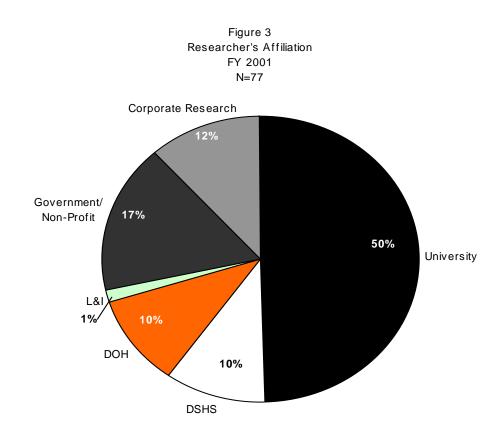


Figure 3 shows the organizational affiliation of the principal investigators for new research proposals received during Fiscal Year 2001. Fifty percent of the principal investigators were university-based, with the University of Washington accounting for the large majority. DSHS-affiliated researchers submitted about 10%, and DOH-affiliated researchers about 10%, of the new proposals reviewed during Fiscal Year 2001.



X. RESEARCH PROPOSALS: FISCAL YEAR 2001

New research proposals reviewed by the Board during Fiscal Year 2001 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 2001.

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 project code in parentheses.

Research submitted for review in Fiscal Year 2001 focused on several program areas within DSHS. Several projects involved evaluating services or outcomes among foster children (B-080100-S; A-032101-S; A-062501-S) or on issues regarding children and families at risk (A-091900-S; B-122100-S; B-051001-S; A-051801-S) Other projects focused on recipients of Medicaid benefits and costs for Medicaid services (B-083100-S; B-092700-S; B-102500-S; A-122400-S; B-020101-S; A-020201-S; A-050901-S).

Projects involving incarcerated populations focused on mentally ill adults (B-091100-S; A-041701-S), incarceration of pregnant women and birth outcomes (A-111500-S) and youth involved in the criminal justice system (B-091900-S; B-020901-S; B-021001-S; A-061201-S).

Women's health issues were a continuing focus of research reviewed this fiscal year, ranging from reproductive health (B-120800-H; B-122500-H; A-040401-H), domestic violence (A-073100-H; B-102800-H), teen mothers (B-103000-S), and cancer (B-042001-H).

Confidential DOH records were utilized in a variety of projects ranging from cerebral aneurysm (B-070900-H), location of death (A-101100-H), a longitudinal study of early childhood (B-122200-H), and poison-induced cardiac arrests (B-011601-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 DSHS/DOH Human Research Review Board During Fiscal Year 2001

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)

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 and Health Statistics
HSQA Health Systems Quality Assurance
EHP Environmental Health Programs

Department of Labor and Industries

SHARP Safety and Health Assessment & Research for Prevention

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, 2001 Status
B-070500-L	"Evaluation of Non-Fatal Residential Injuries and Illness: 1995-1997", Regina McMichael, Aurus Safety Management, Inc. (Clemson, SC)	SHARP	Ongoing
B-070700-S	"Impact of Terminating Substance Abuse Disability Benefits", by Robert G. Orwin, Ph.D., WESTAT (Rockville, MD)	DASA	Ongoing
В-070900-Н	"The Effect of Endovascular Services and Hospital Volume on Cerebral Aneurysm Treatment Outcomes", by David Tirschwell, M.D., M.Sc., Department of Neurology, University of Washington	EHS	Ongoing
A-071000-H	"Review of Cases of Moyamoya Disease in CHARS linked with Death Data", by David Tirschwell, M.D., M.Sc., Department of Neurology, University of Washington	EHS	Ongoing
B-071100-S	"Evaluation of an Eastern State Hospital Geropsychiatric Quality Improvement Initiative", by Dennis Dyck, Ph.D., The Washington Institute for Mental Illness Research and Training - Eastern Branch	MHD	Ongoing
A-071900-L	"Supervisor Assessment of Ergonomic Risk Factors", by Peregrin Spielholz, Ph.D., Safety & Health Assessment & Research for Prevention, Department of Labor & Industries	SHARP	Ongoing
A-073100-H	"Latent TB Infection: Two Approaches to Identify and Treat", by Christopher Spitters, M.D., Community and Family Health, DOH	CFH	Canceled
B-073100-H	"Making the Link: The Relationship of Police- reported Intimate Partner Violence and Maternal and Infant Health Outcomes", Sherry Lipsky, PA-C, M.P.H., School of Public Health, University of Washington	EHS	Ongoing
B-080100-S	"Mental Health of Children in Foster Care in Washington State", by Gunnar Almgren, Ph.D., School of Social Work, University of Washington	CA	Ongoing

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2001 Status
B-080800-S	"Evaluation of the Impacts of Nursing Facility Medicaid Payment System", by Kathryn M. Wade, Meyers & Stauffer LC (Topeka, KS)	A&AS	Ongoing
A-082400-S	"Washington State Child Care Career and Wage Ladder Pilot Project Evaluation", by Brenda J. Boyd, Ph.D., Department of Human Development, Washington State University	CA	Ongoing
A-083000-S	"Evaluation of the Impact of the WWU Rehabilitation Counseling Training Program", by Geri Hansen, Ed.D., Center for Continuing Education in Rehabilitation, Western Washington University	DVR	Ongoing
B-083100-S	"Medicaid Cost Containment Study", by William E. Lafferty, M.D., DOH Services, University of Washington	MAA	Ongoing
B-091100-S	"Dangerously Mentally III Offenders: Evaluation of SSB5011", by Gregg J Gagliardi, Ph.D., The Washington Institute for Mental Illness Research and Training - Western Branch	MHD	Ongoing
A-091400-H	"Reinventing Surveillance Systems for Communicable Disease Prevention", by Maria Courogen, M.P.H., Infectious Disease and Reproductive Health, DOH	CFH	Exempt
A-091500-S	"Assessing the Needs of Persons Who Have Experienced Traumatic Brain Injury", by Stephen M. Bowman, M.H.A., Division of Vocational Rehabilitation, DSHS	DVR	Canceled
B-091600-S	"The Core Indicators Project: Phase III", by Mary Richardson, Ph.D., Center for Disability Policy & Research, University of Washington	DDD	Ongoing
A-091700-S	"Study of Program Access and Declining Food Stamp Participation", by Susan Bartlett, Ph.D., Abt Associates, Inc. (Cambridge, MA)	ESA	Ongoing

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2001 Status
A-091900-S	"HOPE Centers & Responsible Living Skills Programs: Follow-Up with Youth & Parents", by Sylvie McGee, M.S.W., All for a Good Cause Consulting (Seattle, WA)	CA	Ongoing
B-091900-S	"Assessment of Mental & Behavioral Disorders among Incarcerated Male Juveniles", by Catherine A. MacLennan, M.A., Fielding Institute (Santa Barbara, CA)	JRA	Ongoing
A-092100-S	"Welfare to Work Transportation System Service Type Selection", by Mika Miyasato, Department of Urban Design and Planning, University of Washington	ESA	Ongoing
B-092700-S	"A Longitudinal Analysis of Depression Diagnosis in Children", by Dimitri Christakis, M.D., M.P.H., Child Health Institute, University of Washington	MAA	Ongoing
A-101100-H	"Influence of Hospital Bed Availability on Location of Death", by Chris Feudtner, M.D., Ph.D., M.P.H., Child Health Institute, University of Washington	EHS	Ongoing
B-102500-S	"Factors Associated with First and Subsequent Pregnancies among Public Assistance Recipients", by Rachel Gold, M.P.H., School of Social Work, University of Washington	MAA	Ongoing
A-102600-H	"Multi-Session Group Level HIV Risk Reduction Intervention to MSM Youth and their Sex and Needle-Sharing Partners", by Nanci LaMusga, Stonewall Youth (Olympia, WA)	CFH	Canceled
A-102700-H	"Friend to Friend Evaluation", by Elizabeth J. Moore, Ph.D., School of Social Work, University of Washington	CFH	Ongoing
B-102800-H	"Perinatal Partnership Against Domestic Violence", by Judith M. Leconte, M.S.W., Community and Family Health, DOH	CFH	Ongoing
B-103000-S	"Young Teen Mothers Needs Assessment", by Pamela Jull, Ph.D., Office of Survey Research, Western Washington University	ESA	Ongoing

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2001 Status
A-111500-S	"The Effect of Jail Incarceration on Birth Outcomes", by Janice Bell, M.N., School of Nursing, University of Washington	MAA	Ongoing
A-111700-H	"Is Homelessness Associated with Increased Mortality from Community Acquired Pneumonia?", by J. Daryl Thornton, M.D., Department of Medicine, University of Washington	EHS	Ongoing
B-112900-H	"Hospital Care Received by Children Prior to Death", by Chris Feudtner, M.D., Ph.D., M.P.H., Child Health Institute, University of Washington	EHS	Ongoing
A-120700-S	"Developing a Training & Support Program for Providers of Informal Child Care in Washington State", by Richard N. Brandon, Ph.D., Evans School of Public Affairs, University of Washington	CA	Ongoing
B-120800-H	"Obstetrics and Gynecology Specialty Services: Supply, Distribution, and the Effect of Changing Demography", by L. Gary Hart, Ph.D., Department of Family Medicine, University of Washington	EHS	Exempt
A-122100-H	"Sentinel Counties Surveillance for Acute Viral Hepatitis", by Karen Mottram, R.N., B.S.N., Tacoma-Pierce County Health Department	EHS	Ongoing
B-122100-S	"Following Outcomes for "Becca Bill" Youth", by Mason Burley, M.P.A., Washington State Institute for Public Policy	CA	Ongoing
B-122200-H	"Early Childhood Longitudinal Study, Birth Cohort", by Marion MacDorman, Ph.D., National Center for Health Statistics, Centers for Disease Control and Prevention	EHS	Ongoing
A-122300-S	"Evaluation of Metropolitan Development Council's Foster Parent Retention Program", by David N. Fine, Ph.D., Center for Health Training (Seattle, WA)	CA	Canceled
B-122300-H	"Genetic Factors in Meningococcal Disease", by Jairam Lingappa, M.D., Ph.D., Meningitis and Special Pathogens Branch, Centers for Disease Control and Prevention	EHS	Ongoing

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2001 Status
A-122400-H	"Improving Self-Management and Health Lifestyle in Medicaid and Dual Enrolled Medicare People with Disabilities", by Gayle E. Reiber, M.P.H., Ph.D., Health Services, University of Washington	MAA	Ongoing
A-122500-H	"Effects of Pregnancy Intention on Birth Outcome", by Tamarind Keating, School of Public Health, University of Washington	CFH	Ongoing
B-122700-S	"Spokane Substance Abuse Triage Team Services (SATTS)", by Steven Neumiller, M.A., Inland Northwest Proposal Development (Spokane, WA)	DASA	Ongoing
B-011601-H	"Poison-Induced Cardiac Arrests in KC 1977-98", by Thomas G. Martin, M.D., M.P.H., Medical Toxicology Service, University of Washington	EHS	Ongoing
B-020101-S	"Pregnancy Experiences Among DSHS Recipients Living in King County", by Deborah Greenleaf, R.N., B.S.N., School of Nursing, University of Washington	ESA	Ongoing
A-020201-S	"Multi-Site Study of Medicaid Home and Community-Based Services", by Lisa Maria Alecxih, M.P.A., The Lewin Group (Falls Church, VA)	MAA	Ongoing
A-020301-H	"Tobacco Use Assessment in Seattle's Gay, Lesbian, Bisexual, and Transgender Community", by Julia Dilley, M.E.S., Tobacco Prevention and Control Program, DOH	CFH	Ongoing
A-020501-H	"Columbia Basin Drinking Water Quality and Infant Health Study", by James VanDerslice, Ph.D., Office of Environmental Health Assessment, DOH	EHP	Ongoing
B-020501-S	"Naltrexone Treatment in Community Mental Health: Functional Outcomes and Cost- Effectiveness", by Dennis G. Dyck, Ph.D., The Washington Institute for Mental Illness Research and Training - Eastern Branch	DASA	Ongoing
A-020601-S	"Community Family Partnership Evaluation", by Susan Kemp, Ph.D., School of Social Work, University of Washington	CA	Canceled

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2001 Status
B-020901-S	"JRA Co-Occurring Disorders Transition Project", by Eric W. Trupin, Ph.D., School of Medicine, University of Washington	JRA	Ongoing
B-021001-S	"A Survey of Juvenile Forensic Evaluations of Competency to Proceed to Adjudication from 1990- 2000", by Lynne Sullivan, Ph.D., Child Study and Treatment Center, DSHS	MHD	Ongoing
B-022701-H	"First Smiles: Chlorhexidine and Xylitol Gum as Caries Prevention Strategies in Public Health Clinics", by Melody Scheer, R.D.H., Southwest Washington Health District	CFH	Ongoing
A-030501-H	"Health Care Markets and Quality of Hospital Care for Vulnerable Populations", by Jose J. Escarce, M.D., Ph.D., RAND Corporation (Santa Monica, CA)	EHS	Ongoing
A-031301-S	"The Family Support Opportunity Program Evaluation", by Mary Richardson, Ph.D., Center for Disability Policy and Research, University of Washington	DDD	Canceled
B-031601-H	"Including Children with Special Needs in Childcare Programs: An Outcome Evaluation", by Jeanette M. Valentine, Ph.D., Children's Hospital and Regional Medical Center (Seattle, WA)	CFH	Ongoing
A-032001-S	"Take Charge! Evaluation", by Mary Lawrence Cawthon, M.D., M.P.H., Research and Data Analysis, DSHS	MAA	Canceled
A-032101-S	"Assessing the Educational Attainment of Youth in Foster Care", by Mason Burley, M.P.A., Washington State Institute for Public Policy	CA	Ongoing
A-040401-H	"Comparison of Risk Adjustment Methodologies for Cesarean Delivery Rates", by Jennifer Bailit, M.D., M.P.H., University of North Carolina	EHS	Ongoing
A-040901-S	"King County Blended Funding Project Evaluation", by Ann Vander Stoep, Ph.D., Division of Public Behavioral Health and Justice Policy, University of Washington	CA	Canceled

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2001 Status
A-041701-S	"Atypical Antipsychotic Medications: Evaluation of 2SHB2663", by Polly Phipps, Ph.D., Washington State Institute for Public Policy	MHD	Ongoing
B-042001-H	"Longitudinal Patterns of Breast and Cervical Cancer Screening", by Franco Sassi, Ph.D., Institute for Health Policy Studies (San Francisco, CA)	CFH	Ongoing
B-042701-S	"Evaluation of the Responsible Fatherhood Program - Devoted Dads", by Jessica S. Pearson, Ph.D., Center for Policy Research (Denver, CO)	ESA	Ongoing
B-050301-S	"Investigating Cancer Outcomes Through Linkage of Health Systems Data to the Cancer Surveillance System", by Scott Ramsey, M.D., Ph.D., Fred Hutchinson Cancer Research Center	MAA	Ongoing
A-050701-S	"Community Family Partnership Evaluation", by Susan Kemp, Ph.D., School of Social Work, University of Washington	CA	Ongoing
A-050901-S	"Take Charge! Evaluation", by Mary Lawrence Cawthon, M.D., M.P.H., Research and Data Analysis, DSHS	MAA	Ongoing
A-051001-H	"Evaluation of DOH Antibiotic Resistance Surveillance Network", by Rita Altamore, M.D., M.P.H., Public Health Laboratories, DOH	EHS	Ongoing
B-051001-S	"King County Blended Funding Project Evaluation", by Ann Vander Stoep, Ph.D., Division of Public Behavioral Health and Justice Policy, University of Washington	CA	Ongoing
A-051801-S	"Pilot Test of Child Maltreatment Data Log", by Diana J. English, Ph.D., Office of Children's Administration Research, DSHS	CA	Ongoing
A-052101-H	"Trauma Recovery Survey", by Andrew Michaels, M.D., M.P.H., Legacy Emanual Hospital (Portland, OR)	HSQA	Ongoing

Project Code	Proposal Title and Principal Investigator	Program	July 1, 2001 Status
B-052301-S	"Clark County PACT Program Evaluation", by Dennis G. Dyck, Ph.D., The Washington Institute for Mental Illness Research and Training - Eastern Branch	MHD	Ongoing
A-061101-H	"Obstetrical Anesthesia Outcomes in Washington: An Analysis of Inpatient Hospital Discharge Data from 1993-1999" by Dan Simonson, B.S.N., C.R.N.A., College of Pharmacy, Washington State University	EHS	Ongoing
A-061201-S	"Arts Education/Programming in Public Residential Juvenile Detention Facilities", by Rachel Marie-Crane Williams, Ph.D., University of Iowa	JRA	Ongoing
B-061301-S	"Differential Rates of Utilization by Latinos of Inpatient vs. Outpatient Mental Health", by Michael Marquez, B.A., Washington State University	MHD	Ongoing
B-061501-H	"Costs of Motor Vehicle Injuries due to Lack of Restraint Use", by Frederick P. Rivara, M.D., M.P.H., Harborview Injury Prevention and Research Center	EHS	Ongoing
A-061801-H	"Markets and Managed Care", by Laurence C. Baker, Ph.D., Stanford University	EHS	Ongoing
A-062201-H	"Health Seeking Behaviors of Farmworkers Experiencing Pesticide Related Illness", by James VanDerslice, Ph.D., Office of Environmental Health Assessment, DOH	EHP	Ongoing
B-062201-H	"Blinded HIV Seroprevalence Survey in Incoming Inmates in a Washington State Correctional Facility" by Maria Courogen, M.P.H., Infectious Disease and Reproductive Health, DOH	CFH	Ongoing
A-062501-S	"Birth Family/Foster Family Connection Intervention Research Project", by Susan P. Kemp, Ph.D., School of Social Work, University of Washington	CA	Ongoing

