

### Activity Report: DSHS Human Research Review Board

**Fiscal Years 1987-1988** 



Office of Planning, Evaluation and Professional Development

### ACTIVITY REPORT DSHS HUMAN RESEARCH REVIEW BOARD FISCAL YEARS 1987 AND 1988

October 1988

Office of Research and Data Analysis Department of Social and Health Services Olympia, Washington 98505

### STATE OF WASHINGTON Booth Gardner, Governor

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PLANNING, EVALUATION AND PROFESSIONAL DEVELOPMENT Joe Bell, Director

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HUMAN RESEARCH REVIEW SECTION Michael A. Garrick, Coordinator

When ordering, please refer to Report #11-19

### **ACKNOWLEDGEMENTS**

This report is dedicated to the past and present members of the DSHS Human Research Review Board, who have contributed their time and expertise to represent the interests of those who are asked to participate as subjects in research conducted within the jurisdiction of the Department of Social and Health Services.



## STATE OF WASHINGTON

# DEPARTMENT OF SOCIAL AND HEALTH SERVICES

## OLYMPIA, WASHINGTON

(Updated August 1988)

# Human Research Review Board

Chairperson		Executive Secretary	
Robert N. Doupe', M.S.W. Administrator, Program Support DSHS Juvenile Rehabilitation (Appointment to December 31, 1988)	t 1988)	Michael A. Garrick, Ph.D. Coordinator, Human Research Review Section DSHS Planning, Evaluation and Professional Development (Permanent Appointment)	ew Section ofessional intment)
Members	Expiration of Appointment Term	Members	Expiration of Appointment Term
Cathy Blinka, J.D. Resident Advocate Rainier School DSHS Developmental Disabilities	May 31, 1989	Judith V. Olmstead, Ph.D. Research Investigator Office of Research & Data Analysis DSHS Planning, Eval. and Prof. Dev.	Oct. 15, 1990
Todd Allen Damrow, Ph.D. Microbiology Research Coordinator Public Health Laboratories DSHS Health Services	Nov. 30, 1988	William Quick, M.S.W. Program Manager DSHS Children & Family Services	Nov. 15, 1988
2Ronald Dear, D.S.W. Associate Professor School of Social Work	June 30, 1989	Dan Rubin, M.P.P. Executive Director DSHS State Health Coordinating Council	May 31, 1990
University of Washington  2 David Fallen, Ph.D.  Research Director	Dec. 31, 1989	Rebecca Ann Rudner, Ph.D. Clinical Psychologist Western State Hospital DSHS Mental Health	Nov. 30, 1988
Washington Sentencing Guidelines Commission , 2Robert Leahy, M.D.	Jan. 31, 1989	2Robert A. Stalker, Jr., J.D. Litigation Coordinator Evergreen Legal Services	May 31, 1989
Physician  2Frederica Wieneke O'Connor, R.N., Ph.D. Assistant Professor Psychosocial Nursing	June 30, 1991	Julie C. Will, Ph.D. Epidemiologist Chronic Disease Control DSHS Health Services	Nov. 30, 1988
James Owens, M.D. Echo Glen Children's Center DSHS Juvenile Rehabilitation	May 31, 1989	3Jon Ostlund, J.D. Director Whatcom County Public Defender	July 31, 1991

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### **EXECUTIVE SUMMARY**

State law, administrative regulations and department policy require that the DSHS Human Research Review Board review and approve all research (except certain limited categories) involving department clients, employees or confidential records, and all research funded by the department, or contracted to outside parties, whether or not department clients, employees or confidential records are involved.

This review process is intended to protect the rights 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 DSHS Human Research Review Board is comprised of professionals working both within and outside the department. Board members volunteer a substantial amount of their time to review proposals submitted by researchers. The present membership of the Board is shown on page v.

The Board receives administrative support from the Human Research Review Section. The Coordinator of the Section also serves as the Executive Secretary of the Board.

This report summarizes the Board's authority and functions, describes the review process, and provides an overview of major activities during FY 1987-1988. It also includes a log of all research projects which were under review during this two year period.

More information about the department's human research review policies and procedures, and copies of the <u>Guide to DSHS</u> <u>Policy on Protection of Human Research Subjects</u> and the <u>department's Research Application Kit, may be obtained by contacting the Human Research Review Section, OB-35, or by calling (SCAN) 234-0424.</u>

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### ACTIVITY REPORT

Department of Social and Health Services

Human Research Review Board

Fiscal Years 1987 and 1988

### I. PURPOSE

The Department of Social and Health Services is responsible for protecting the rights and welfare of clients, employees, and members of the general public who serve as subjects in research within the department's jurisdiction. The department has fulfilled this responsibility by establishing a formal policy for the protection of human subjects, and by maintaining a standing Human Research Review Board, which operates under the auspices of an Assurance of Compliance with the federal Department of Health and Human Services.

The DSHS Human Research Review Board has primary responsibility for implementing the department's human subjects protection policy. The Review Board conducts an ethical and a technical review of proposed research projects 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 the light of stated project objectives.

### II. AUTHORITY

The department's human subjects protection policy complies with federal regulation (45 CFR 46) and with protective requirements of state law (e.g., RCW 42.48; RCW 71.05.030). Washington Administrative Code (WAC 388-10) and DSHS Administrative Policy 12.01 prohibit any service or administrative unit within the department from allowing the conduct of research and related activities until the plans or protocols have been approved by the Review Board. The department's policy and procedures are described more fully in the Guide to DSHS Policy on Protection of Human Research Subjects. The department's policy on protecting human research subjects is generally referred to as the human research review policy.

### III. ACTIVITIES SUBJECT TO BOARD REVIEW

Except for research activities specifically exempted in the <u>Guide to DSHS Policy...</u>, Section V, the department's human research review policy applies to all research and related activities that involve department clients, wards, or employees as human subjects, or that require disclosure of their personal records, or disclosure of other nonpublic records in the department's custody. Research conducted by department staff which involves subjects who are not department clients is also subject to the review policy. The policy also applies to research and related activities contracted by the department to non-departmental organizations or individuals, regardless of whether the research involves DSHS clients or a nondepartmental subject population.

A description of activities subject to Board review is contained in the <u>Guide to DSHS Policy...</u>, Sections I and III. This document, however, often does not provide enough guidance in distinguishing 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, <u>Jurisdictional Guidelines</u> have been developed to assist researchers and program managers in determining the boundaries of Review Board jurisdiction. These guidelines are available on request from the Human Research Review Section.

### IV. ADMINISTRATION

The DSHS Human Research Review Section is a small administrative unit consisting of a coordinator and a half-time secretary. The Coordinator of the Review Section provides staff support to the Review Board, and coordinates and administers the department's human research review policy. The Coordinator provides liaison between the department and other agencies and institutions on human subjects protection issues. The Coordinator also serves as the Executive Secretary of the Review Board.

Research proposals requiring Board review must be submitted on the department's application forms. Research Application Kits are available from the Review Section. The Coordinator of the Review Section is 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 call the Review Section. Copies of the <u>Guide to DSHS Policy...</u>, and all other documents described in this report, may be obtained from the Review Section, by calling (206) 753-0424 (SCAN 234-0424) during regular business hours.

### V. REVIEW BOARD FUNCTIONS

The primary function of the DSHS Human Research Review Board is to protect the interests of individuals participating in research within the department's jurisdiction. An important secondary function is to provide DSHS management with the necessary expertise to determine whether proposed research is valid, worthwhile, and in compliance with federal and state statutes and regulations.

Department administrators, managers and supervisors should refer all inquiries regarding human subjects research to the Coordinator of the Review Section. The Review Board is responsible for reviewing proposed human subjects research, and for defining procedures to assure that the research is conducted in accord with applicable statutes and regulations.

### VI. REVIEW BOARD MEMBERSHIP

The Review Board is comprised of at least 12, but not more than 18 members, including the Chair and the Executive Secretary, but not including ad hoc members who review only selected proposals. Board members are chosen to represent the diversity of programs administered by the department, and to provide the necessary expertise to conduct a thorough ethical and technical review of proposed research.

The 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 and research methods, and several are employed full time in scientific research positions. The 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 two or more community representatives who are unencumbered by possible departmental interests. The current membership of the Board is listed on page v.

### VII. REVIEW PROCESS

Investigators wishing to conduct human subjects research within the department's jurisdiction must submit an application to the Review Section. Depending on the nature, scope and complexity of the proposed research, applications are either referred to the full Review Board for consideration at a regularly scheduled meeting, or are reviewed by the Board Chair and Executive Secretary through the expedited process (See <u>Guide to DSHS Policy...</u>, Section IV(1) 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 present the proposal to the Board at the meeting. This "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 to provide supplementary information.

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., disapprovals, 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 review and concurrence by the appropriate DSHS 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: FY 1987-1988

During the past two years, the Review Section has published guideline documents which address two of the most frequent and troublesome issues which arise during the course of Board reviews. The first is the question of what activities fall within the jurisdiction of the Board; the second is the Board's authority to conduct technical reviews of research proposals.

The Coordinator of the Review Section drafted <u>Jurisdictional Guidelines</u> to address the first issue. This document was reviewed by members of the Board and by selected departmental staff, and was subsequently revised. The final document published in March 1987 extended the logic of the ethical distinction between research and clinical medical practice to the distinction between research and common departmental activities, such as administrative data collection and program monitoring. The paradigm used in the <u>Jurisdictional Guidelines</u> is broad and flexible enough to be applied successfully to most jurisdictional questions which arise.

One of the more vexing issues which arises during the course of Board business involves disputes over the Board's authority to review the scientific or technical aspects of research proposals. Many researchers argue that the Board's mandate is limited to the ethical review of proposals, and object strenuously when the Board raises concerns regarding sampling or research design.

The Board's authority to conduct technical reviews is rooted in the same tradition as its mandate to review the ethical aspects of proposed research. This interrelationship is widely misunderstood in the research community. Because the Board weighs the risks to research subjects in relation to the anticipated benefits of the research, the Board must examine the design of each study to determine whether benefits are likely to be produced. If a study is flawed, the benefits which could accrue from the research are The technical standard applied in the Board's questionable. review is related to the potential risks imposed on subjects by the proposed research. Thus, the Board's technical review must determine beyond reasonable doubt that the proposed research design has sufficient validity to justify exposing subjects to the risks inherent in the activity.

The Coordinator of the Review Section drafted Technical and Ethical Review Guidelines to explain the review process and the standards that are applied, and to provide a rationale for the Board's technical review responsibilities. The draft Guidelines were submitted for review and comment to the department's division directors, assistant secretaries, and selected researchers, as well as to the twelve most recent Written responses were received applicants to the Board. from twenty-five individuals, the majority of whom concurred with the Board's authority to conduct technical reviews of The Guidelines were revised on the basis research proposals. of written comments received, and were published in February This document is included in each Research Application Kit, and copies may be obtained from the Review Section.

Early in Fiscal Year 1987, the Coordinator of the Review Section began negotiating the renewal of the department's Multiple Project Assurance of Compliance with the National Institutes of Health. This interagency agreement between the Department of Social and Health Services and the federal Department of Health and Human Services is generally granted for a period of three to five years.

The renewal process involved responding to requests for information from DHHS, and providing renewed assurance that DSHS will support the Human Research Review Board, and will comply with federal regulations regarding the protection of human research subjects. The new Assurance of Compliance was signed in May 1987, and remains in effect until July 31, 1992.

As part of the renewal process, the <u>Guide to DSHS Policy...</u> was revised and updated. The relatively minor revisions were intended to bring the document into conformity with a state statute (RCW 42.48), and to improve the consistency between the document and applicable federal regulations (45 CFR 46). The department's basic human research review policy and procedures were not affected by these revisions. The revised <u>Guide</u>, published in August 1987, reflects the current DSHS policy regarding the conduct of research involving human subjects.

The Review Board's bylaws are defined in the publication Functions, Responsibilities & Bylaws of the DSHS Human Research Review Board. This document was revised to increase the maximum size of the Board, to increase the maximum term of Board membership, and to clarify the disposition of confidential material handled by the Board. The revised Bylaws were published in February 1988.

The Board experienced considerable turnover in its membership during the past two years, with nine new members joining the Board during FY 1988 alone. Part of this turnover is explained by the expiration of the terms of several long-standing members. However, the size of the Board also has increased from twelve to sixteen members, both in response to an increasing workload, and to improve the representativeness of the Board.

Recommendations for Board membership are solicited from current Board members, and from department managers and researchers. Recommendations should be submitted to the Review Section for consideration by the Review Board.

### IX. REVIEW VOLUME

Table 1 summarizes five measures of Review Board activity over the past fifteen years. Review volume has fluctuated over time, with the general pattern being that of a U-shaped curve. The trends in review activity correlate rather closely with the waxing and waning of funds available to support research.

Total projects under review (A), and new proposals received (B), peaked in the late 1970's, reached a low point in the early 1980's, and have increased more or less steadily since then. The total number of Board reviews (C) follows a similar pattern, but has increased more sharply since the early 1980's, and reached a historical high point during the past two years.

Review activity increased significantly between 1985-1986 and 1987-1988. The number of proposals received increased 23%, and the number of Board reviews increased 30%, during this

TABLE 1

# SUMMARY OF RESEARCH REVIEW ACTIVITIES

30     1981     1982     1983     1984     1985     1986     1987       1     51     60     76     81     87     88     92       3     28     24     26     30     26     27     31       5     44     77     47     88     65     96       7     3     5     5     12     9     10       5     6     4     3     4     3     2     2						Fiscal	1	Years 1	1974-1988	1988			-		
1975         1976         1977         1978         1980         1981         1982         1983         1984         1985         1986         1987           32         56         90         105         107         61         51         60         76         81         87         88         92           24         45         50         35         33         38         28         24         26         30         26         27         31           44         83         67         43         61         80         56         44         77         47         88         65         96           5         9         2         7         3         37         7         3         5         5         5         10           1         1         5         6         9         6         6         4         3         4         3         4         3         2         2															
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44         83         67         43         61         80         56         44         77         47         88         65         96           5         9         2         7         3         37         7         3         5         5         12         9         10           1         1         5         6         9         6         6         4         3         4         3         2         2	 19	24		50	35	33	38	28	24	26	30	26	27	31	34
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and TOTAL PROJECTS UNDER REVIEW Includes all projects ongoing at the end of the fiscal year, and all projects pending, completed, cancelled, disapproved during the fiscal year.

the NEW PROPOSALS RECEIVED Includes all new proposals received by Human Research Review Section during the fiscal year. æ.

TOTAL BOARD REVIEWS Includes all full Board and expedited reviews of progress reports, preapplication reviews, and reviews of issues requiring Board action. new proposals, and subcommittee reviews of Board required revisions as well as reviews of annual proposals, ີ່

# D. CANCELLED PROJECTS

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period. The immediate prospect appears to be for a steady increase in research activity and corresponding review volume.

Several trends recently have emerged in the type of research proposals submitted. Most notably, the Board has reviewed a number of proposals to conduct AIDS related projects. Several surveys of attitudes, knowledge and behavior in relationship to AIDS, both among various high risk groups as well as among the general public, have been reviewed. The Board also has reviewed a project which estimated the prevalence of HIV infection among new inmates at the Washington Correction Center, and continues to review the department's participation in the Family of HIV Seroprevalence Studies sponsored by the Centers for Disease Control.

The Board also has seen an increasing number of proposals related to the department's major program initiatives. A legislatively mandated evaluation of the Family Independence Program, and an internal departmental FIP evaluation, have been reviewed. Numerous proposals related to the department's child welfare reform and child protective services initiatives have been reviewed. These proposals have been submitted both by internal departmental researchers and by university affiliated researchers.

These trends are expected to continue through the next two year period, as scarce research dollars are focused on the evaluation of high priority program initiatives.

### X. PROJECT LOG

The Project Log, which begins on page 13, lists the projects which were "active" in the Human Research Review Section during the past two years. Included are projects carried forward from previous years, as well as projects which were submitted for review during FY 1987-1988. Each of these projects was reviewed one or more times during this two year period.

Table 2 shows the disposition of these projects as of June 30, 1988. Almost half of the "active" projects were ongoing, i.e., continuing, at the end of FY 1988. Approximately 30% were completed, and about 9% were cancelled, by the end of the period. An additional 9% were pending final disposition, i.e., they remained in various stages of review and had yet to receive final approval to proceed.

Figure 1 shows the distribution of research projects by DSHS program area. The largest number of research projects within the department's jurisdiction is in public health. Many of these are epidemiological studies which are conducted by students and faculty at the University of Washington, and

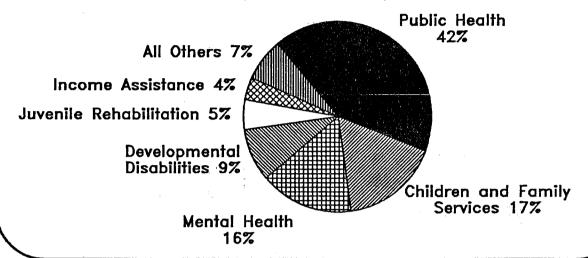
TABLE 2

PROJECT DISPOSITION (as of June 30, 1988)

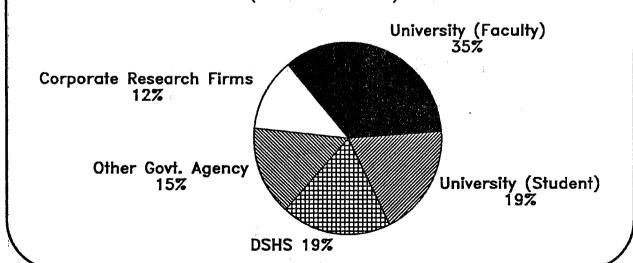
(CAI	OLD PE	OLD PROJECTS (CARRIED FORWARD FROM	NEW I	NEW PROJECTS (SUBMITTED DURING	TOTAL ]	TOTAL PROJECTS
	PREVIOUS N	S YEARS)	FY 19 N	)87-1988) %	z	%
ONGOING	24	37.5	40	61.5	64	49.6
COMPLETED	31	48.4	7	10.8	38	29.5
CANCELLED	6	14.1	က	4.6	12	6.3
DISAPPROVED	0	0	က	4.6	ო	2.3
PENDING	0	0	12	18.5	12	9.3
TOTAL	64	100	65	100	129	100
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### FIGURE 1. RESEARCH PROJECTS BY DSHS PROGRAM: FY 1987-1988

(N = 129)



## FIGURE 2. RESEARCHERS' ORGANIZATIONAL AFFILIATION: FY 1987-1988 ( N = 129 )



which require access to confidential records maintained by the department. Vital Records computer files are the most common source of data for epidemiological studies. There also is substantial research activity in Children and Family Services, Mental Health and Developmental Disabilities.

Figure 2 shows the organizational affiliation of researchers conducting projects within the department's jurisdiction. Organizational affiliation is distinct from funding source; for example, some research conducted by individuals affiliated with a university is done under contract with the department. Likewise, some internal DSHS research is conducted with grant funds from the federal government.

More than half of the researchers are university affiliated, with the University of Washington accounting for the large majority. DSHS provides an important source of data for students of graduate and post graduate programs. About 20% of the research under Board review is conducted by university graduate students for thesis and dissertation projects. Graduate student research typically involves studies which require access to the department's confidential records, and research which requests client participation in surveys.

About 20% of the active projects during FY 1987-1988 were conducted by DSHS researchers. However, this proportion underestimates the magnitude of department sponsored research because it does not include projects contracted to outside researchers. Research conducted by department staff for graduate credit is listed as being performed by university students rather than by DSHS.

### PROJECT LOG

List of Projects Reviewed by the DSHS Human Research Review Board During Fiscal Years 1987 and 1988



<u>Date of</u> <u>Receipt</u>	Proposal Title and Principal Investigator	Current Status
5-2-77	"Sudden Infant Death Risk Factor Study", by Donald R. Peterson, M.D., Department of Epidemiology, Univer- sity of Washington, Seattle, WA	Ongoing
11-20-78	"Intergenerational Factors in Pregnancy Outcome", by Irvin Emanuel, M.D., Child Development & Mental Retardation Center, University of Washington, Seattle, WA	Completed 6-9-87
12-26-79	"Birth Control and the Risk of Infertility", by Janet R. Daling, Ph.D., Department of Epidemiology, University of Washington, Seattle, WA	Completed 2-2-87
2-28-80	"Studies of Reproductive Outcome in the Hanford Nuclear Population: Case-Control Study of Birth Defects and Fetal and Infant Deaths", by Ethel S. Gilbert, Ph.D., Battelle Pacific Northwest Laboratories, Richland, WA	Ongoing
2-13-81	"The Effects of Assertiveness Training on Mentally Ill Offenders' Self-Esteem Level as Measured by the Tennessee Self-Concept Scale", by Milton C. Brown, Jr., U.S. International University, San Diego, California	Cancelled 6-2-88
3-30-81	"A Study to Evaluate the Impact of the Rural Health Clinic Services Act of 1977 on Rural Clinics in HEW Region X", by Malcolm Peterson, M.D., Ph.D., Division of Community Medicine, University of Washington, Seattle, WA	Ongoing
5-18-81	"An Analysis of Role Conceptualizations Among Family Care Providers for Differing Client Populations", by Mary Ann Re, Department of Sociology, St. John's University, Jamaica, New York	Completed 6-16-88

Date of Receipt	Proposal Title and Principal Investigator	<u>Current</u> <u>Status</u>
8-14-81	"Surveillance of Childhood Cancer Incidence as it Relates to Birth Certificate Data", by Janet R. Daling, Ph.D., Department of Epidemiology, University of Washington, Seattle, WA, and Patricia Starzyk, Ph.D., Health Data Section, DSHS Public Health	Ongoing
3-26-82	"Cephalostat for Dental Care of the Developmentally Disabled", by Frederic A. Harris, Ph.D., Department of Restorative Dentistry", University of Washington, Seattle, WA	Ongoing
5-5-82	"The Social Ecology of Residential Environments", by Sharon Landesman, Ph.D., Frank Porter Graham Child Development Center, University of North Carolina, Chapel Hill, N.C.	Ongoing
5-12-82	"The Effects of Elicitation Prompts, Social Consequences, and Token Reinforcement on the Training and Transfer of Requesting Behavior in Severely Mentally Retarded Individuals", by Susan E. Kellogg, Fircrest School, Seattle, WA	Cancelled 7-10-86
9-20-82	"Risk Factors for Complex Febrile Seizures: A Case-Control Study", by Thomas D. Koepsell, M.D., Department of Epidemiology, University of Washington, Seattle, WA	Ongoing
2-3-83	"The Sexually Abused Child in Treatment", by Rolf Frohlich, Ph.D., Sexual Abuse Prevention and Treat- ment Program, Tacoma School Dis- trict, Tacoma, WA	Cancelled 7-14-86
5-3-83	"American Indian Alcoholism: Statewide Treatment Utilization", by R. Dale Walker, M.D., Alcohol Treatment Program, Veterans Admin- istration Medical Center, Seattle, WA	Ongoing

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Date of Receipt	Proposal Title and Principal Investigator	Current Status
5-9-83	"Survey of Hospitalized Cases of Pelvic Inflammatory Disease in Washington State in 1982", by Kristine Wicklund, Ph.D., Epidemiology Section, DSHS Public Health	Completed 1-27-88
8-4-83	"Comparative Dispositions Study", by Joseph White, The Academy, Inc., Columbus, Ohio	Completed 7-31-86
8-15-83	"Recurrence Risk in Sudden Infant Death Syndrome", by Janet R. Daling, Ph.D., Department of Epidemiology, University of Washington, Seattle, WA	Completed 8-27-86
8-30-83	"Assessment of Fetal and Maternal Effects of Gestational Hyper-glycemia", by Thomas Benedetti, M.D., Department of Obstetrics & Gynecology, University of Washington, Seattle, WA	Completed 4-7-88
9-15-83	"Program, Caseworker, Client and Employer Contributions to Employment: An Experimental Comparison of Work Experience and Job Search Assistance Strategies", by Nancy S. Dickinson, School of Social Work, University of Washington, Seattle, WA	Completed 7-14-86
9-19-83	"Multicenter Study: Effects of Fenfluramine on Autism", by Paul Hageman, M.D., Rainier School, Buckley, WA	Cancelled
9-19-83	"Multicenter Study: Effects of Fenfluramine on Autism", by Marvin Bruno, Ph.D., and Sean Killoran, M.D., Frances Haddon Morgan Center, Bremerton, WA	Completed 7-15-87
10-6-83	"DJR Learning Centers Evaluation", by John Steiger, Ph.D., DSHS Juvenile Rehabilitation	Completed

<u>Date of</u> <u>Receipt</u>	Proposal Title and Principal Investigator	<u>Current</u> <u>Status</u>
12-16-83	"National Study of Institutional Commitment and Release Decision-Making for Adjudicated Delinquents", by Bruce Fisher, J.D., URSA Institute, San Francisco, California	Completed 8-8-86
2-3-84	"Case Control Study of Diabetic Individuals to Identify Risk Factors Associated with Lower Extremity Amputations", by Gayle E. Reiber, M.P.H., Veterans Administration Medical Center, Seattle, WA	Ongoing
3-6-84	"Infant Birth Weight: Familial, Host and Environmental Variables", by Ruth E. Little, Sc.D., Alcoholism & Drug Abuse Institute, University of Washington, Seattle, WA	Completed 3-30-87
3-29-84	"Congenital Adrenal Hyperplasia: Newborn Mass Screening", by Jack Allard, Ph.D., Public Health Laboratories, DSHS Public Health	Ongoing
4-19-84	"Epidemiologic Investigation of Health Effects in Air Force Person- nel Following Exposure to Her- bicides", by George D. Lathrup, M.D., Epidemiology Division, Brooks AFB, Texas	Ongoing
6-25-84	"Commencement Bay-Nearshore/Tide- flats Superfund Project Ruston/Vas- hon Exposure Pathways Study", by Lincoln Polissar, Ph.D., Department of Biostatistics, University of Washington, Seattle, WA	Completed 9-3-87
7-6-84	"The Impact of Mental Disability on the Family", by Lois Price Spratlen, R.N., Ph.D., Department of Psycho- social Nursing, University of Washington, Seattle, WA	Ongoing
7-26-84	"Adolescent Drug Abuse Treatment and Early Intervention", by J. David Hawkins, Ph.D., and Richard Catalano, Ph.D., School of Social Work, University of Washington, Seattle, WA	Ongoing

Date of Receipt	Proposal Title and Principal Investigator	<u>Current</u> <u>Status</u>
8-2-84	"Mortality in a Cohort of Orchard Workers Exposed to Lead Arsenate Spray", by Kristine Tollestrup, Ph.D., Epidemiology Section, DSHS Public Health	Ongoing
8-13-84	"Tacoma Community House Volunteer Refugee Tutoring Study", by Peter M. Skaer, Ph.D., Tacoma Community House, Tacoma, WA	Completed 9-8-86
9-17-84	"Genital Herpes During Pregnancy: Historical Cohort Study of Newborn and Maternal Outcomes", by Lawrence Corey, M.D., Virology Division, Children's Orthopedic Hospital, Seattle, WA	Ongoing
2-4-85	"Prevalence and Clinical Characteristics of Gastrointestinal Infections Caused by Escherichia coli 0157:H7", by Michael O'Leary, M.D., M.P.H., Epidemiology Section, DSHS Public Health	Completed 9-28-87
2-19-85	"Proposal to Study Differences in Reactivity to Two Commercial PPD Tuberculins (PPD-S)", by Robert Leahy, M.D., Office of Disease Prevention and Control, DSHS Public Health	Cancelled 10-2-86
3-25-85	"Rural Infant Care Evaluation", by Steven Gortmaker, Ph.D., Department of Behavioral Sciences, Harvard School of Public Health, Boston, Massachusetts	Ongoing
5-2-85	"Absenteeism in DSHS: A Study of Possible Risk Factors", by Barbara Dicker, Seattle University, Seattle, WA	Completed 10-21-86
5-3-85	"Analysis of Factors Contributing to the Failure of Family-Based Child Welfare Services", by David Haapala, Ph.D., Behavioral Sciences Insti- tute, Federal Way, WA	Ongoing

Date of Receipt	Proposal Title and Principal Investigator	<u>Current</u> <u>Status</u>
5-4-85	"Home Based Services Evaluation", by Beverly Kooi, Ph.D., DSHS Office of Research and Data Analysis	Completed 8-15-86
5-6-85	"Improving the Measurement of Violent Behavior", by Joseph G. Weis, Ph.D., and George S. Bridges, Ph.D., Department of Sociology, University of Washington, Seattle, WA	Ongoing
5-16-85	"Regional Perinatal Management Data", by Frederick A. Connell, M.D., M.P.H., Department of Health Services, University of Washington, Seattle, WA	Completed 10-24-86
5-23-85	"Infant 'Lactation' as Protection Against Breast Cancer: A Preliminary Study of Known Breast Cancer Cases", by Irvin Emanuel, M.D., Fred Hutchinson Cancer Research Center, Seattle, WA	Completed 7-22-86
7-15-85	"The Relationship of Perinatal Outcome to Obstetrical Volume and Neonatal Technology in the Birthing Hospital", by Jennifer A. Mayfield, M.D., and Roger Rosenblatt, M.D., The Robert Wood Johnson Clinical Scholars Program, University of Washington, Seattle, WA	Completed 11-20-86
7-23-85	"Natural History and Variation in Seizure Frequency", by Mark S. Yerby, M.D., Department of Neurolog- ical Surgery/Neurology, University of Washington, Seattle, WA	Cancelled 4-7-88
8-7-85	"Cardiovascular Fitness in Adoles- cence", by Albert Hergenroeder, M.D., Child Development and Mental Retardation Center, University of Washington, Seattle, WA	Completed 10-1-87
9-12-85	"Population Based Birth Defects Surveillance", by Mary O'Mara, M.P.H., Birth Defects Monitoring Program, DSHS Public Health	Completed 8-4-86

<u>Date of</u> <u>Receipt</u>	Proposal Title and Principal Investigator	Current Status
9-13-85	Premature Mortality in Persons with Diabetes: A Pilot Study", by Julie C. Will, Ph.D., Epidemiology Section, DSHS Public Health	Completed 9-4-87
9-16-85	"Juvenile Sex Offender Treatment Evaluation", by Donna D. Schram, Ph.D., Urban Policy Research, Seattle, WA	Ongoing
9-17-85	"Consequences of Severe Mental Disability in Afro-American Families", by Helen S. Murphy, R.N., Department of Psychosocial Nursing, University of Washington, Seattle, WA	Completed 10-15-86
10-1-85	"Epidemiology of Childhood In- juries", by Rob Brison, M.D., Department of Epidemiology, Univer- sity of Washington, Seattle, WA	Completed 7-24-86
10-29-85	"Rural Infant Care Project: The Prevention of Low Birth Weight and the Reduction of Fetal Death Rate in the Central Washington Perinatal Program", by William Shaul, M.D., Department of Pediatrics, University of Washington, Seattle, WA	Cancelled 2-22-88
11-1-85	"Toxic Shock Syndrome and Bacterial Meningitis Study", by John Kobaya-shi, M.D., M.P.H., Epidemiology Section, DSHS Public Health	Completed 4-7-88
11-4-85	"Postrotatory Nystagmus and Motor Performance: A Comparison Between Preschoolers in Mental Health Programs and Preschoolers in Non-Mental Health Programs", by Lois Arms Kramer, O.T.R., Department of Rehabilitative Medicine, University of Washington, Seattle, WA	Completed 2-18-87
12-21-85	"Communication Skills Development for School-Age Deaf-Blind Children and Youth", by Rebecca R. Fewell, Ph.D., Experimental Education Unit, University of Washington, Seattle, WA	Completed 4-6-88

Date of Receipt	Proposal Title and Principal Investigator	<u>Current</u> <u>Status</u>
12-22-85	"Incidence and Predictors of Post-Cortical Resection Psychosis in Patients with Epilepsy", by Linda Moretti Ojemann, M.D., Harborview Medical Center, Seattle, WA	Ongoing
12-23-85	"Intermittent vs. Maintenance Medication in Schizophrenia", by Robert Waters, M.D., Harborview Medical Center, Seattle, WA	Cancelled 6-22-87
2-3-86	"Cancer Control and Prevention Demonstration Project", by Robert Leahy, M.D., and Kristine Tolles- trup, Ph.D., Epidemiology Section, DSHS Public Health	Cancelled 8-18-86
2-4-86	"NIMH Mental Health Survey", by Linda Pemerl, Quality Assurance Department, Western State Hospital, Ft Steilacoom, WA	Ongoing
2-5-86	"The Relationship Between Depression and Behavioral Functioning in Persons with Dementia of the Alzheimer's Type", by Ruth Chaffee, Good Samaritan Mental Health Center, Puyallup, WA	Completed 5-14-87
2-13-86	"Elder Abuse: The Effects of Man- datory Reporting", by Karen Fredrik- sen, School of Social Work, Univer- sity of Washington, Seattle, WA	Completed 6-11-87
2-14-86	"Analysis of Infant Mortality Trends in King County, 1977-1984", by Eduardo Alcantar, M.D., Department of Community Medicine, University of Washington, Seattle, WA	Completed 4-13-87
3-12-86	"A Study of Casualties in Residential Fires in Seattle-King County", by Jane E. Ballard, Epidemiology Section, DSHS Public Health	Ongoing
3-13-86	"Use of Health Services by Medicaid Beneficiaries", by Thomas Bice, Ph.D., Department of Health Services, University of Washington, Seattle, WA	Ongoing

Date of Receipt	Proposal Title and Principal Investigator	<u>Current</u> <u>Status</u>
3-25-86	"Adolescent Pregnancy Demonstration Project", by Dennis McBride, Ph.D., Evaluation Consultant, DSHS Parent & Child Health Services	Ongoing
6-18-86*	"Perceptual Scaling of Violent and/or Aggressive Events by Court Committed Psychiatric Patients"	Disap- proved 7-17-86
· 7–1–86	"Prenatal Care Program Evaluation", by Kathe Dobbs, R.N.C., M.P.H., DSHS Parent & Child Health Services	Completed 8-12-87
8-1-86	"A Description of the Obstetrical Practices of Family Physicians and Obstetricians in Washington State, and the Effect of the Liability Environment on These Practices", by Laura-Mae Baldwin, M.D., Department of Family Medicine, University of Washington, Seattle, WA	Ongoing
8-11-86	"Fountain House Survey", by Jolyn Wells, M.S.W., Valley Cities Mental Health Center, Auburn, WA	Ongoing
9-2-86	"Investigation of Occupational Electromagnetic Field Exposure and Brain Tumor Occurrence", by Robert R. Schommer, Department of Community Health Nursing, University of Washington, Seattle, WA	Completed 9-11-87
9-12-86	"Homebuilders Adoption Service Continuum", by David Haapala, Ph.D., Behavioral Sciences Institute, Federal Way, WA	Cancelled 10-2-86
9-15-86	"Perception of Violent Incidents by Psychiatric Patients with Assaultive and Nonassaultive Histories", by Richard V. Alumbaugh, Ph.D., Department of Psychology, Central Washington University, Ellensburg, WA	Cancelled 11-6-86

<sup>\*</sup>Counted as received in FY 1987

Date of Receipt	Proposal Title and Principal Investigator	<u>Current</u> <u>Status</u>
10-30-86	"Intra-Hospital Relocation of Psychiatric Patients and Effects on Aggression", by Mary Durand Thomas, Ph.D., R.N., C.S., Department of Psychosocial Nursing, University of Washington, Seattle, WA	Ongoing
10-31-86	"Washington State Behavioral Risk Factor Surveillance System", by Kristine Tollestrup, Ph.D., Epidemi- ology Section, DSHS Public Health	Ongoing
10-31-86	"Rainier Follow-Along Pilot Project"	D i s a p - proved 11-20-86
11-3-86	"Survey of Indian Child Welfare and Implementation of the Indian Child Welfare Act and Section 428 of the Adoption Assistance and Child Welfare Act of 1980", by Ruth Hubbell, Ph.D., CSR, Inc. Washington, D.C.	Cancelled 11-18-86
11-4-86	"Lymphoma/Immunosuppression Pilot Study", by Samuel Milham, Jr., M.D., M.P.H., Epidemiology Section, DSHS Public Health	Ongoing
11-18-86	"Study of Neurologic Illness & Vaccination", by James Gale, M.D., Department of Epidemiology, University of Washington, Seattle, WA	Ongoing
12-1-86	"Study on Washington State Food Stamp Work Registrant Characteris- tics", by Joseph E. Trimble, Ph.D., Department of Psychology, Western Washington University, Bellingham, WA	Completed 10-27-87
12-8-86	"Maternal Mortality Collaborative", by Roger W. Rochat, M.D., School of Medicine, Emory University, Atlanta, Georgia	Ongoing
12-11-86	"Children's Mental Health Needs Assessment", by Eric Trupin, Ph.D., Department of Psychiatry and Behavioral Sciences, University of Washington, Seattle, WA	Ongoing

Date of Receipt	Proposal Title and Principal Investigator	Current Status
12-18-86	"Homebuilders Adoption Service Continuum", by David Haapala, Ph.D., Behavioral Sciences Institute, Federal Way, WA	Ongoing
12-19-86	"Rainier Follow-Along Pilot Pro- ject", by Bruce Treichler, Develop- mental Disabilities Planning Council, Olympia, WA	Ongoing
1-13-87	"Assessing the Impact of Insanity Defense Reforms", by Lisa A. Callahan, Ph.D., NYS Office of Mental Health, Albany, NY	Ongoing
1-28-87	"Evaluation of Regionalization of Perinatal Care", by Anita F. Penuelas, Department of Health Services, University of Washington, Seattle, WA	Ongoing
2-2-87	"Social Skills and Social Isolation in Physically Abusive Families", by Geoffrey A. Wiegand, M.A., Division of Community Psychiatry, University of Washington, Seattle, WA	Ongoing
2-6-87	"Children's Mental Health Needs Assessment: The Parent Perspec- tive", by Eric Trupin, Ph.D., Department of Psychiatry & Be- havioral Sciences, University of Washington, Seattle, WA	Completed 6-3-88
3-11-87	"Survey of Knowledge, Attitudes and Practices Concerning AIDS Among Gay/Lesbian Individuals Outside of Seattle-King County", by Deenie M. T. Dudley, M.A., Office on AIDS, DSHS Public Health	Completed 3-23-88
3-13-87	"National Medical Expenditure Survey", by Doris R. Northrup, M.A., Westat, Rockville, MD	Ongoing
3-17-87	"Washington State AIDS Knowledge and Opinion Survey, by John F. Peppert, Office on AIDS, DSHS Public Health	Completed 7-24-87

<u>Date of</u> <u>Receipt</u>	Proposal Title and Principal Investigator	<u>Current</u> <u>Status</u>
5-6-87	"Effects of AIDS Prevention Education on IV Drug Users", by Terry Reid, Tacoma-Pierce County Health Department, Tacoma, WA	Pending
5-12-87	"Career Path Project (CPP)", by Kristen A. West, The Evergreen State College, Olympia, WA	Ongoing
5-18-87	"An Evaluation of Client Feedback Statements for MMPI Test Results", by Lisa B. Christian, M.S., Depart- ment of Psychology, Washington State University, Pullman, WA	Ongoing
6-10-87	"Epidemiology of Hypertension In Pregnancy: Risk Factors", by Noreen Harris, Ph.D., Tacoma-Pierce County Health Department, Tacoma, WA	Pending
6-22-87	"Early Intervention Project"	Disap- proved 7-9-87
6-23-87	"Family Independence Program Survey Project", by Mary Lynn Waterhouse, Seattle, WA	Completed 6-29-88
6-26-87	"Stress/Morale Questionnaire", by Ron Nellermoe, Gonzaga University, Spokane, WA	Ongoing
7-30-87	"The Black Child in the Foster Care System", by Clarice D. Walker, M.S., National Black Child Development Institute, Washington, D.C.	Ongoing
7-31-87	"A Prevalence Study of Human Immunodeficiency Virus (HIV) Infected Male Inmates Entering the Department of Corrections at the Washington Corrections Center (WCC)", by Kenneth Peterson, M.P.H., Department of Corrections, Olympia, WA	Ongoing
8-4-87	"National Evaluation of the Impact of Guardians Ad Litem in Child Abuse or Neglect Judicial Proceedings", by Larry Condelli, Ph.D., CSR, Incorporated, Washington, D.C.	Ongoing

Date of Receipt	Proposal Title and Principal Investigator	<u>Current</u> <u>Status</u>
8-6-87	"Mental Health Services to the Mentally Ill Elderly", by Rochelle L. Crosby, Ph.D., Community Home Health Care, Seattle, WA	Ongoing
8-25-87	National Child Abuse Mortality Study", by Richard D. Krugman, M.D., Kempe National Center for the Prevention and Treatment of Child Abuse, Denver, Colorado	Ongoing
9-3-87	"Early Intervention Project", by Bill Horner, D.S.W., School of Social Work & Human Services, Eastern Washington University, Cheney, WA	Ongoing
9-10-87	"The Childhaven Project: Research on Prevention and Intervention Policies for Families of Handicapped and At-Risk Children Who are Abused or Neglected", by Eugene Edgar, Ph.D., Experimental Education Unit, University of Washington, Seattle, WA	Ongoing
9-16-87	"AIDS Prevention Curriculum for High-Risk Adolescents", by Robert J. Bidwell, M.D., Division of Adolescent Medicine, University of Washington, Seattle, WA	Ongoing
9-21-87	"Family Independence Program Base- line Survey", by David Pavelchek, DSHS Office of Research & Data Analysis	Pending
10-2-87	"Assaultive Resident Behavior Relating to Employee Injuries", by Beth Wensly, Department of Environmental Health, University of Washington, Seattle, WA	Ongoing
10-28-87	"An Analysis of the Washington State Scoliosis Screening Program", by Robert Lowell Davis, M.D., Epidemi- ology Section, DSHS Public Health	Ongoing
11-2-87	"Survey of Juveniles in Custody", by Lawrence S. McGinn, Bureau of the Census, Washington, D.C.	Ongoing

<u>Date of</u> <u>Receipt</u>	Proposal Title and Principal Investigator	<u>Current</u> <u>Status</u>
11-4-87	"Centers for Disease Control HIV Seroprevalence Studies", by William E. Lafferty, M.D., Office on AIDS, DSHS Public Health	Ongoing
12-2-87	"Evaluation of the Culturally Enhanced Mental Health Projects", by Joseph W. Scott, Ph.D., Ethnic Consulting Research Service, Seattle, WA	Ongoing
12-18-87	"Efficacy of an Electron Generator Device in Reduction of Symptoms Attributable to Suboptimal Indoor Air Quality", by William E. Daniell, M.D., M.P.H., Department of Environ- mental Health, University of Washington, Seattle, WA	Ongoing
12-18-87	"Washington State Longitudinal Study", by Greg C. Weeks, Ph.D., The Evergreen State College, Olympia, WA	Ongoing
12-21-87	"Prospects Versus Progress in Supported Employment", by Joseph J. Stowitschek, Ed.D., Transition Institute, University of Washington, Seattle, WA	Pending
12-22-87	"Mental Health Division Case Management Demonstration Evalua- tion", by Jack Fuller, Ph.D., DSHS Office of Research & Data Analysis	Ongoing
1-27-88	"Evaluation of Key States Initia- tive", by Michael H. de Marr, Touche Ross & Co., Seattle, WA	Pending
2-1-88	"Compassionate Use of Clozapine", by Singa Krishnamoorti, M.D., Western State Hospital, Ft. Steilacoom, WA	Pending
3-2-88	"Office VDT Use and Reported Symptoms", by Harvey Checkoway, Ph.D., Department of Environmental Health, University of Washington, Seattle, WA	Ongoing

Date of Receipt	Proposal Title and Principal Investigator	<u>Current</u> <u>Status</u>
3-3-88	"Comparison of Charges and Patient Characteristics Between Teaching and Non-Teaching Settings for the Delivery of Obstetrical Care", by Gilad S. Gordon, M.D., The Robert Wood Johnson Clinical Scholars Program, University of Washington, Seattle, WA	Ongoing
3-10-88	"Preventing Sexual Victimization of Young Children: Sex Offender Substudy", by Jon Conte, Ph.D., University of Chicago, Chicago, Illinois	Pending
3-25-88	"Sexual Allegations Project", by Nancy Thoennes, Ph.D., Association of Family Conciliation Courts, Denver, Colorado	Ongoing
3-29-88	"The Quality of Prenatal Care Received by Medicaid Beneficiaries in Prepaid Health Plans in the State of Washington", by James Krieger, M.D., The Robert Wood Johnson Clinical Scholars Program, University of Washington, Seattle, WA	Ongoing
3-30-88	"Seattle Urban League/POCAAN AIDS Knowledge and Attitude Survey", by Karen A. Hartfield, M.P.H., Seattle Urban League, Seattle, WA	Ongoing
4-7-88	"Pregnancy Complications and Obstetrical Outcomes of Homeless Women in Seattle/King County", by Edythe Schlossstein, School of Public Health, University of Washington, Seattle, WA	Pending
4-29-88	"Northwest Regional Primary Care Association Community/Migrant Health Centers HIV Seroprevalence Study and Attitude, Knowledge and Behavior Survey", by Jayne B. Leet, M.B.A., Northwest Regional Primary Care Association, Seattle, WA	Pending

Date of Receipt	Proposal Title and Principal Investigator	<u>Current</u> <u>Status</u>
5-16-88	"Determining Developmental Status of Child Protective Services Clients", by Margaret A. West, M.S.W., Ph.D., Child Development & Mental Retarda- tion Center, University of Washing- ton, Seattle, WA	Ongoing
5-20-88	"Prevention and Treatment of Rural Child Sexual Abuse", by JoAnn Ray, Ph.D., and Susan Murty, M.S.W., School of Social Work, Eastern Washington University, Cheney, WA	Pending
5-31-88	"Medicaid Transfer of Assets Study", by Steve Moses, Department of Health and Human Services, Seattle, WA	Ongoing
6-15-88	"Educating for Ownership: The Use of Nonformal Education in the Fountain House Model of Psychiatric Rehabili- tation", by Charles H. Kinzel, College of Education, University of Washington, Seattle, WA	Pending
6-27-88	"Evaluation of Intensive Protective Payees for ADATSA Clients", by Aaron Lowin, Ph.D., DSHS Office of Research & Data Analysis	Pending

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