Activity Report
Washington State Institutional Review Board
Fiscal Year 2006

Washington State Department of Social and Health Services
MANAGEMENT SERVICES ADMINISTRATION
RESEARCH AND DATA ANALYSIS DIVISION
HUMAN RESEARCH REVIEW SECTION

ACTIVITY REPORT

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

WASHINGTON STATE INSTITUTIONAL REVIEW BOARD

Fiscal Year 2006

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

When ordering please refer to
Report # 11.130

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ACKNOWLEDGEMENTS

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

Updated August 2006

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EXECUTIVE SUMMARY

THIS REPORT PROVIDES AN OVERVIEW OF THE WASHINGTON STATE INSTITUTIONAL REVIEW BOARD. IT SUMMARIZES THE BOARD'S AUTHORITY AND FUNCTIONS, OUTLINES THE HUMAN RESEARCH REVIEW PROCESS, AND DESCRIBES MAJOR ACTIVITIES DURING FISCAL YEAR 2006. IT ALSO INCLUDES A LOG OF ALL RESEARCH PROJECTS WHICH WERE REVIEWED DURING THIS PERIOD.

The Washington State Institutional Review Board operates under the *Washington State Agency Policy on Protection of Human Research Subjects*. This policy applies: 1) Whenever the Washington State Institutional Review Board provides review and oversight of human subject research, regardless of where the research takes place or by whom it is conducted, and 2) Whenever these Washington State agencies become engaged in human subject research. An agency becomes engaged in research whenever (a) the employees or agents of the agency intervene or interact with living individuals for purposes of research; (b) the employees or agents of the agency access, release, or obtain individually identifiable private information for purposes of research; or (c) the agency receives a direct federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

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

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

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

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

ACTIVITY REPORT

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

Washington State Institutional Review Board

Fiscal Year 2006

I. PURPOSE

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

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

II. AUTHORITY

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

III. ACTIVITIES SUBJECT TO BOARD REVIEW

Except for research activities specifically exempted in the *Washington State Agency Policy on Protection of Human Research Subjects,* Section XI, the departments' human research review policy applies: 1) Whenever the Washington State Institutional Review Board provides review and oversight of human subject research, regardless of where the research takes place or by whom it is conducted, and 2) Whenever these Washington State Agencies become engaged in human subject research. An agency becomes engaged in research whenever (a) the employees or agents of the agency intervene or interact with living individuals for purposes of research; (b) the employees or agents of the agency obtain, release, or access individually identifiable private information for purposes of research; or (c) the agency receives a direct federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

A definition of research and a list of categories of research that are exempt from review are provided in the *Washington State Agency Policy on Protection of Human Research Subjects,* Sections IV and XI, respectively. In addition, the *CDC Guidelines for Defining Public Health Research and Public Health Non-Research* is helpful in distinguishing between public health research and public health practice. However, these documents may not always provide enough information to distinguish between research and related activities that are subject to review and administrative data collection or program monitoring activities that are not subject to review. If in doubt, researchers and department staff should contact Review Section staff (360 902-8075) to discuss the boundaries of Review Board jurisdiction. Researchers and department staff should submit an *Exempt Determination Request* if they are unsure of whether the proposed activity is considered research under the departments' policy. A written response to this request will be provided within five working days.

IV. ADMINISTRATION

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

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

V. REVIEW BOARD FUNCTIONS

The primary function of the Washington State Institutional Review Board is to protect the interests of individuals participating in research within the departments' jurisdiction. The Review Board performs this function by reviewing proposed research plans, and, if necessary, by assisting researchers in revising their plans to conform to accepted ethical standards and regulatory requirements. An important secondary function of the Review Board is to provide DSHS/DOH/L&I management with the necessary expertise to determine whether proposed research is valid, worthwhile, and in compliance with federal and state statutes and regulations. DSHS/DOH/L&I administrators, managers, and supervisors are encouraged to refer all inquiries regarding human subjects research to the Review Section.

VI. REVIEW BOARD MEMBERSHIP

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

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

VII. REVIEW PROCESS

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

Proposals that require full Board review are pre-reviewed before they are placed on the agenda of a Board meeting. An electronic copy of a proposal for full Board review must be submitted no later than the application deadline for the meeting. Researchers will be informed of the results of the pre-review no later than one week after the application

deadline. Researchers then have one week to revise their application before the proposal is sent to Board members prior to the meeting. One member is asked to be the "primary reviewer" and to present the proposal to the Board at the meeting. Researchers are asked to be available by telephone to provide factual information and to clarify issues during review of their proposal at the Board meeting. Occasionally, the researcher is invited to attend the meeting to respond to questions or concerns or to provide supplementary information.

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

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

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

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

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

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

The *Washington State Institutional Review Board Procedures Manual* (April 2004) provides additional details regarding the review process, management and support of the Review Board, Review Board operations, and standards for conducting research in the departments' jurisdiction.

VIII. MAJOR ACTIVITIES: FISCAL YEAR 2006

Human Subject Protection Activities at the National Level

During the spring and summer of 2005, the Environmental Protection Agency was strongly criticized when it developed plans to propose new regulations to permit testing of pesticides on human beings--including pregnant women and young children. In June 2005, Senator Barbara Boxer (D-California) introduced a bill to place a moratorium on all human testing until final regulations could be developed. The Bush administration would re-start human testing, which was prohibited under a moratorium issued during the Clinton Administration. Given the level of national protest, the EPA was pressured to cancel a human study of pesticide exposure. The CHEERS study (Children's Environmental Exposure Research Study) would have paid parents to use pesticides so that researchers could track exposures in infants. Many subjects in CHEERS were low income or otherwise disadvantaged. The EPA administrator revealed that the EPA was conducting more than 250 other human studies--many of them sponsored by the chemical industry--which exposed subjects to potentially harmful substances. Under federal regulations, EPA is permitted to require producers of pesticides to conduct studies with human subjects. In a June report to Congress, Senator Boxer and Representative Waxman revealed ethical lapses in previous studies sponsored by EPA and industry.

The EPA issued its proposed regulations in September 2005. Under these regulations, any research supported by EPA would explicitly prohibit intentional dosing studies that included pregnant women or children as subjects. Further, the regulations would apply 45 CFR Part 46, Protection of Human Research Subjects, to research conducted by third parties that is not financed or otherwise supported by the EPA if research findings would be subsequently submitted to the EPA. Third-party researchers would be required to describe the ethical conduct of human subjects research in their EPA submissions. Although the EPA would not require intentional dosing studies involving human subjects, the proposed regulation would consider data voluntarily submitted by researchers when assessing toxicity of chemical substances and environmental exposure to humans. EPA would also establish an internal Human Studies Review Board to review intentional dosing studies after local IRB review has occurred. The final rule was issued in February 2006. It prohibits research on pesticides which involve intentional exposure of pregnant women or children. EPA would accept "otherwise unacceptable research" if: the agency received input from their advisory Human Studies Review Board; the public had an opportunity to comment; the data are crucial to the decision as to whether to require stronger regulatory protection of the public health; and the agency publishes an explanation of how it reached its decision. Also in February, EPA announced that its HSRB was in place; its first meeting was held in April 2006.

Controversy surrounding the Health Insurance Portability and Accountability Act of 1996 (HIPAA) continues. The Association of American Medical Colleges and other professional groups are pushing for changes to the HIPAA Privacy Rule, in order to facilitate human subjects research. AAMC and others believe that HIPAA creates a stumbling black to vital clinical research, creation of disease registries for research, as well as inhibiting epidemiologic, health services, and genetics research. These groups argue that the Privacy Rule does not truly increase privacy protections for patients, but does impose substantial burden. AAMC recommendations were incorporated into the Secretary's Advisory Committee on Human Research Protection recommendations to HHS Secretary Thompson. (In our admittedly anecdotal experience, the problems lie in misunderstanding of the HIPAA Privacy Rule, rather than the Rule itself.)

A researcher was sentenced to nearly six years in prison for criminally negligent homicide, which resulted from his falsification of lab results and the subsequent death of a research participant. Paul H. Kornak was permanently disbarred from all transactions with the federal government upon a finding of scientific misconduct by the Office of Research Integrity. Mr. Kornak lied about a previous felony conviction when he applied for his post at the Stratton VA Medical Center in Albany, New York. It was found that over a three-year period Mr. Kornak falsified clinical information in order to enroll subjects who were ineligible for clinical trials in which he was research coordinator. One research subject, James J. DiGeorgio, died less than two weeks after enrolling in a clinical trial. Mr. Kornak had falsified lab results showing impaired kidney and liver function, which would have made Mr. DiGeorgio ineligible for the research.

The Department of Education worked on modifications to regulations in the Protection of Pupil Rights Act, which would prohibit schools from requiring student participation in surveys, analyses, or evaluations without the prior permission of their parents. A Notice of Proposed Rule Making was expected by mid-2006.

Congress

Representative Waxman co-sponsored the Fair Access to Clinical Trials Act, H.R. 3196, during the summer of 2005 with fairly broad support in the House. The Act would require all human subjects research to be registered on a federal registry prior to initiation of the trial. The Act incorporates monetary penalties for non-compliance, and requires registration of clinical trials regardless of funding source. Each sponsor would be required to submit a detailed description of subject eligibility, study design, procedures and methods, outcomes to be assessed, and information regarding the specific disease or condition for which the drug, device, or biologic is intended. The Act also would require information in the registry to be understandable to the lay public. IRB's would be required to verify that a study is registered prior to granting approval. Phase I studies would not be subject to national registration requirements.

Senator Sam Brownback (R-Kansas), introduced the "Access, Compassion, Care, and Ethics for Seriously Ill Patients Act" in November 2005. The bill would speed the FDA approval process for drugs, medical devices, and biological products, and would prohibit placebo-only and no-treatment control trials. Under the bill, a three-tiered approval system would be implemented, making it easier for seriously ill patients to obtain materials or products

under investigation without enrolling in a clinical trial. Draft language for Tier 1 approval places emphasis on patient autonomy to choose whether to use an investigational product: "the use of available investigational products for treatment is the responsibility of the physician and the patient", rather than the responsibility of a regulatory body or a clinical investigator.

In May 2006, Senator John Cornyn (R-Texas) introduced the "Federal Research Public Access Act of 2006" which would require federal agencies funding research to develop policies for public access to research findings. The bill would apply to investigators who obtain *any* federal funding to conduct research. The bill focuses on broader access to research publications, rather than permitting public access to research data.

Office of Human Research Protections

In May 2005, the Office of Human Research Protections issued guidance for IRBs, institutional officials and institutions regarding when and how to report unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR Part 46 or the requirements or determinations of the institutional review board (IRB); and suspension or termination of IRB approval. The guidance describes when the reporting requirements apply to a research protocol; information to be included in incident reports; a time frame for reporting; OHRP's focus on corrective actions when reviewing incident reports; and OHRP's response to such reports. Report content would vary by the type of report: for example, issues of non-compliance have different reporting requirements than reports of serious unanticipated adverse events that pose risks to subjects. The majority of external adverse events would not need to be submitted to the IRB, and in many cases do not contain sufficiently detailed information to permit an IRB to determine whether the events may require a re-assessment of risks to subjects. The guidance may be downloaded at *http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html*.

OHRP also issued guidance in May 2005 regarding "407 Reviews". An IRB may request a 407 Review when it finds that a protocol involving children is "not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem" (45 CFR 46.407). In such cases, the Secretary of HHS convenes a panel to review the protocol and seeks public comment, usually by publication of the protocol and request for comment in the *Federal Register*. OHRP consults with FDA, as research involving an FDA-regulated product or device must also meet FDA human subjects protection requirements. If FDA regulations apply, OHRP would delegate 407 Review responsibilities to the FDA. The guidance also permits federal funding agencies to delay or suspend human subjects research at all sites of a multisite study when only one (or more) site IRBs request a 407 Review. Under a 407 Review, all relevant IRB information related to the protocol must be open to public access.

In November 2005, OHRP co-sponsored a two-day workshop focusing on alternative IRB models. The workshop brought together entities that have expressed concern in the past about regulatory burden, heavy workloads, and resource shortages among IRBs. The workshop identified 10 potential models for alternative approaches, among them: local IRBs share materials and share information to facilitate review of multi-site studies; an

institution agrees to rely on review of a single study by another institution; a single independent IRB reviews for one or more sites in a multi-site study; a local IRB accepts, reviews, or modifies the decision made by a central IRB. Workshop participants also considered the implications of alternative models, such as loss of local control and input on multi-site studies, and sensitivity to the local community context. In some cases, "redundant" reviews may actually provide a safety net for researchers and institutions.

OHRP provided additional information regarding exempt research involving children. The "Question and Answer" document on OHRP's website clarifies that research would not be exempt if it involves interviews or survey procedures, or if the researchers interact with child subjects during observations of public behavior (see 45 CFR 46.101(b)(2). In order to qualify for exemption from human subjects protection requirements, research involving children must meet all other exemption requirements as well. Simply put, if researchers would conduct surveys or interviews with children, or interact with children in public settings in order to observe behavior, the activity would not be exempt.

Hurricanes Katrina and Rita have had an impact on IRBs in Louisiana, Texas, Alabama, and Mississippi, to the extent that OHRP suggested ways in which IRBs in the hurricane-affected areas could remain in compliance with regulatory requirements. Among the suggestions was to refer reviews to an FWA institution in an area that was not impacted by the catastrophe. Institutions may also choose to suspend research, except when continuation may be in the best interests of subjects, as is sometimes the case with clinical trials. Given the widespread property damage and dispersal of local populations, OHRP indicated that it would be flexible in working with institutions to remain in compliance with 45 CFR 46 and recognized that it may be impossible to fulfill some regulatory requirements, such as continuation review.

OHRP announced that institutions that do not renew or establish a Federalwide assurance (FWA) by the January 1, 2006 deadline would be required to suspend all HHS-funded research. The FWA is the only type of assurance approved by OHRP; Multiple Project Assurances and Cooperative Project Assurances all expired on December 31, 2005. The assurance process can now be completed electronically, which is less cumbersome. An institution's IRBs listed on the FWA must first be registered with OHRP.

National Institutes of Health

In December 2005, NIH issued a report on participation of racial and ethnic minority subjects in research. The report, "New Findings on the Willingness of Minorities to Participate in Health Research," found that minorities participate at the same rate as non-Hispanic whites when they are otherwise eligible for research. The study found disparities in research recruitment, rather than refusal to participate once approached. The general assumption has been that minorities are hesitant to participate, or indeed mistrustful of researchers, in large part due to egregious ethical abuses of minority populations in previous studies, going back decades. The report recommends that researchers make an effort to conduct outreach to minority communities, to broaden awareness of research and specific protocols for which individuals may be eligible.

Food and Drug Administration

In July 2005 FDA issued a Public Health Advisory to update patients and healthcare providers with the latest information on antidepressant use and risk of suicide. Even before the publication of these reports, FDA had begun the process of reviewing available data to determine whether there is an increased risk of suicidal behavior in adults taking antidepressants. The agency asked manufacturers to provide information from their trials using an approach similar to that used in the evaluation of the risk of suicidal behavior in the pediatric population taking antidepressants. "Black box" warnings were eventually required for product labeling of antidepressants.

In January 2006 FDA issued guidance on exploratory IND studies. This is part of FDA's overall emphasis on speeding up development of new products. The guidance applies to early Phase I studies involving IND and biological products that assess feasibility for further development. In most cases, such studies would involve limited human exposure, and would not have any diagnostic or therapeutic intent. Rather, these studies would be designed to determine a safe starting dose for humans, to understand which organs may be the targets of toxicity, to estimate the margin of safety between a clinical and a toxic dose, and to understand the pharmacokinetics of a particular compound. Exploratory INDs would be expected to be of short duration, no more than one week.

Human Subject Protection Activities at the Local Level

In July 2005, a conference on pediatric bioethics was held in Seattle. The Center for Pediatric Bioethics is affiliated with Children's Regional Hospital and Medical Center, the first center of its kind in the United States. The conference, "Current Controversies in Pediatric Research Ethics" focused on the regulatory framework for research involving children; equity and justice in research with children; genetic issues; the role of healthy children in clinical research; child assent; antidepressant use in children; and conflict of interest in pediatric research. The Center will hold conferences on pediatric bioethics issues on an annual basis.

The Review Coordinator took the certification exam for IRB professionals in October 2005, and successfully attained CIP certification. PRIM&R's Council for Certification of IRB Professionals (CCIP) established certification criteria and procedures for IRB professionals. The certification process is intended for individuals participating in and overseeing the daily activities associated with an IRB. The rigorous exam assesses knowledge of ethical principles, historical events, regulatory requirements, and operational and functional issues relating to IRBs and other human subjects protection programs. Although certification is voluntary, an increasing number of institutions require certification for IRB staff and sometimes IRB Chairs and members.

The Manager of the Human Research Review Section attended the Public Responsibility in Medicine and Research (PRIM&R) conference in Boston. This national IRB conference was co-sponsored by the Applied Research Ethics National Association (ARENA). Conference topics included informed consent with vulnerable populations; investigator noncompliance

or misconduct; ethical issues in genetics research; research subject recruitment, retention, and follow-up, among dozens of other topics. The annual conference draws approximately 2,500 IRB members, staff, researchers, and compliance officers from across the country and from several foreign countries.

In April 2006, the WSIRB introduced its new, completely revamped research application. The new form includes check boxes that allow researchers to skip sections which are not relevant for their research and incorporates appendices, as needed. For example, the special protections in the federal regulations, 45 CFR 46 Subparts B, C, and D, are appendices which should be completed only if the research involves pregnant women, fetuses and/or neonates; prisoners; or children, respectively. Another Appendix covers all types of waivers which a researcher may request, such as waiver of documentation of consent (a signed consent document), or a waiver of authorization for disclosure of identifiable records. Researchers planning to submit an application for review should ensure that the form is newly downloaded from the WSIRB website for each submission, as corrections and clarifications may be made over time.

IX. REVIEW VOLUME AND TRENDS

Figure 1 provides three measures of Review Board activity during the past 20 years. The total projects under review increased slowly during the period between 1987 and 1990, increased significantly from 1991 through 1999, and has fluctuated since that time while continuing a general upward trend.

Figure 1
Review Volume
Fiscal Years 1987 - 2006

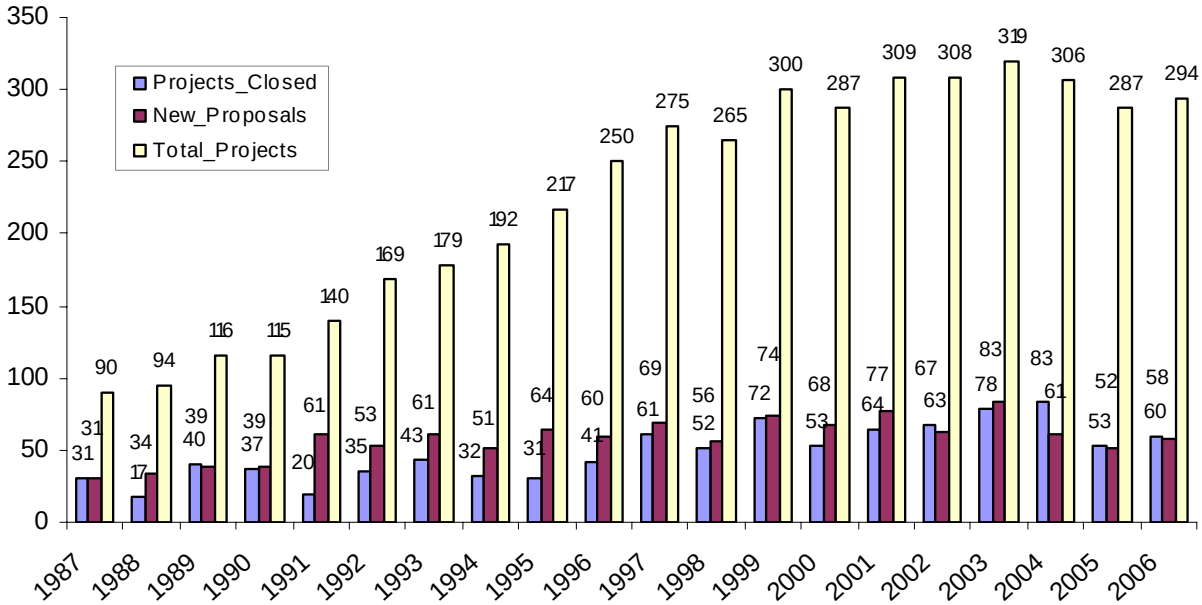


Figure 2 shows the distribution of new research proposals by agency and program for Fiscal Year 2006. The Department of Social and Health Services accounted for 49% of the new proposals reviewed during FY 2006. Children's Administration led DSHS program areas in the amount of research reviewed with 15% and Economic Services Administration and the the Mental Health Division each accounting for 9% of new proposals. About 41% of the new proposals reviewed were in the jurisdiction of the Department of Health, with 20% in Community and Family Health and 13% in Epidemiology and Health Statistics. Six percent of the proposals reviewed were in the jurisdiction of the Department of Labor and Industries.

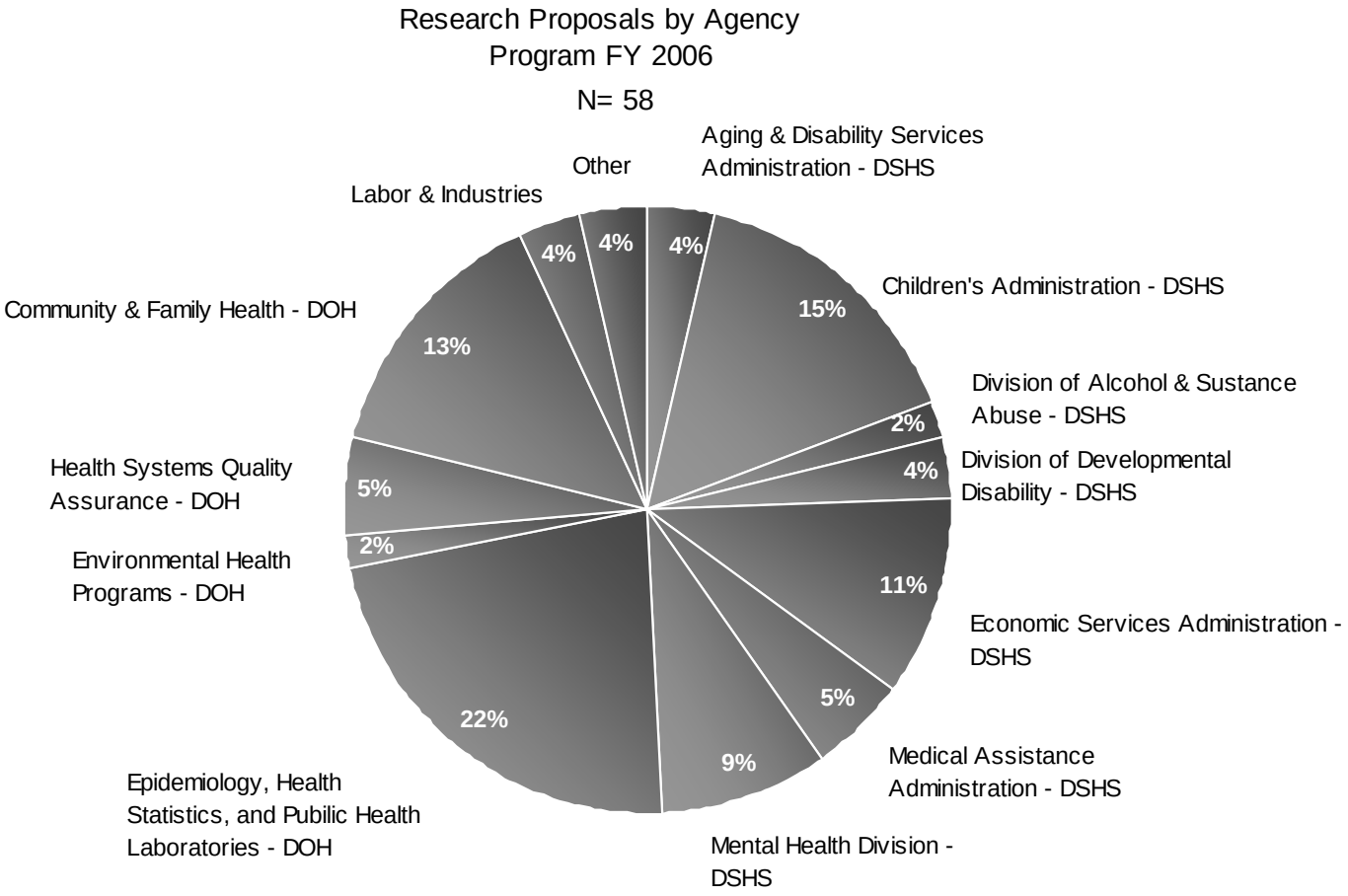
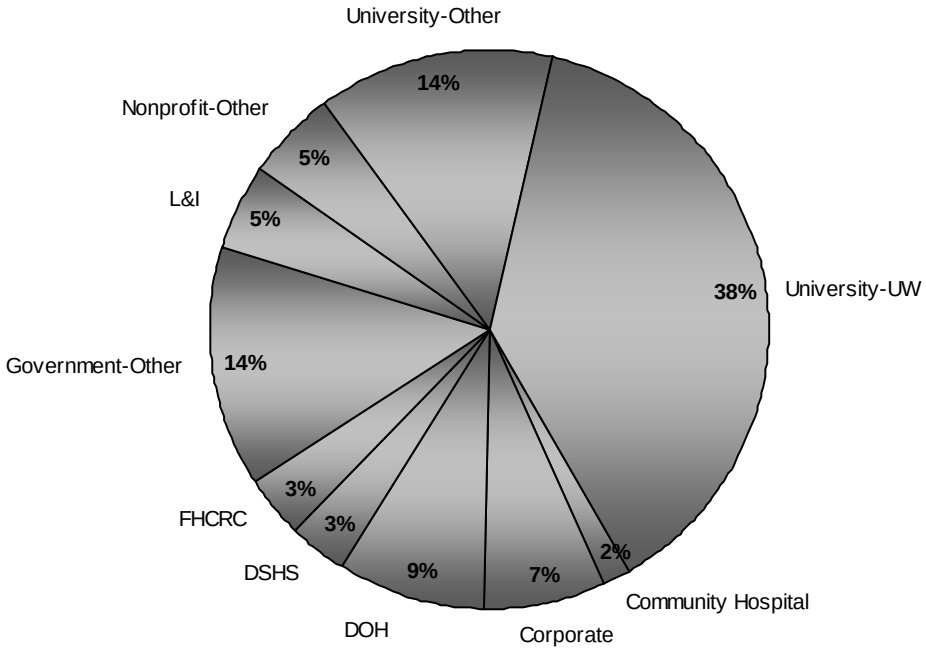


Figure 3 shows the organizational affiliation of the principal investigators for new research proposals received during Fiscal Year 2006. Fifty two percent of the principal investigators were university-based, with the University of Washington accounting for the large majority.

Figure 3
Researchers Affiliation
FY 2006
N= 58



X. RESEARCH PROPOSALS: FISCAL YEAR 2006

New research proposals reviewed by the Board during Fiscal Year 2006 are listed in chronological order of receipt in the Project Log. These new proposals account for approximately one-quarter of the total number of ongoing research projects under the Review Board's jurisdiction at the end of Fiscal Year 2006.

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

Cancer was a focus of several projects reviewed during FY06. Several utilized the Washington State Cancer Registry (A-100305-H, B-112305-H, B-010306-H), linked to other data sources. Other cancer-related research involved contact with subjects to assess knowledge of cancer among persons of color (A-020106-H, A-020906-H), lymphedema

following cancer treatment (A-122005-H), and cancer prevention and screening interventions in the workplace (B-031506-H).

Environmental and occupational health research was submitted for review by investigators from the Department of Labor and Industries and from the University of Washington. Two studies evaluate health effects of air pollution (A-022206-H, A-061206-H), while other studies evaluate workplace fatalities (B-032006-L), preventable causes of pesticide exposure (B-072805-H) and isocyanate exposure (A-013106-L).

Other research projects focused on mental health issues of foster children (B-012406-S), competency evaluations (B-020206-S), patients in state hospitals (B-022406-S, B-050506-S), and a pilot day program for persons with dementia (B-102605-S). Child abuse and neglect was the focus of a large national study (B-112105-S). Other researchers evaluated services for runaway youth (B-102505-S), family court (B-122105-S, B-100505-S), federal initiatives to increase child support and healthy marriages (A-021606-S, A-051506-S), and a national program for teen mothers (B-061906-S).

The Department of Health launched an ambitious study to evaluate cardiovascular disease and diabetes risk in the general population (B-091405-H). The study is conducting home visits to interview Washington residents about their health behaviors and to perform clinical assessments of blood pressure, cholesterol and blood glucose, exposure to mercury, and body mass index.

In addition to the proposals reviewed by the WSIRB listed in the Project Log, Review Section staff also conducted administrative reviews of proposals which were exempt from the requirement for WSIRB review. Thirty-nine studies were found to be exempt during FY06, while four studies submitted for exemption were found to be non-exempt.

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

PROJECT LOG

Research Proposals Reviewed by the Washington State Institutional Review Board during Fiscal Year 2006

PROJECT LOG KEY

Project Code

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

Program

Department of Social and Health Services

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

Department of Health

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

Department of Labor and Industries

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

Unaffiliated Investigators

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

Status

Ongoing	Project pending final approval, or approved and continuing
Cancelled	Project was discontinued
Completed	Project was finished
Suspended	Project approval suspended

Project Log
Activity Report
From 7/1/2005 thru 6/30/2006

Project Code	Project Title	Program	Status
A-071205-S	Net Impact and Cost-Benefit Evaluations of Washington State's Workforce Training System	ESA	Completed
	Evelyn Hawkins — Workforce Training and Education Coordinating Board		
B-072505-H	Abdominal Pain: Predictors of Appendicitis in Children	EHS	Ongoing
	Carolyn Paris — Children's Hospital & Regional Medical Center		
A-072705-U	Evaluation of Children's Oral Health Program in Pierce County	OTH	Cancelled
	Elizabeth Pulos — Tacoma-Pierce County Health Department		
B-072805-H	Identifying Preventable Causes of Pesticide-Related Illness among Agricultural Workers	EHP	Ongoing
	James VanDerslice — DOH / Office of Environmental Health & Safety		
B-072905-H	Surgical Clinical Outcomes Assessment Program	PHS	Cancelled
	David Flum — UW / Department of Surgery		
B-080205-H	Vaccine Safety Surveillance & Assessment Activities	EHS	Ongoing
	Allison Naleway — Kaiser Permanente / Center for Health Research		
B-081005-H	Recidivism Among Burn Patients in the State of Washington	EHS	Cancelled
	Matthew Klein — UW / Harborview Medical Center		
B-081505-S	Design, Development, and Implementation of a Prospective Payment System for Inpatient Psychiatric Hospitals and Exempt Units	MHD	Completed
	Brant Fries — University of Michigan / Institute of Gerontology		
A-081605-H	The Utility and Impact of Standard Trauma Triage Criteria in the Elderly	HSQA	Ongoing
	Matthew Martin — Madigan Army Medical Center		
A-082205-H	Trends in Coronary Revascularization using CABG and PCI in Washington State	EHS	Cancelled
	Gabriel Aldea — UW / Department of Surgery		
B-082505-H	A Comparison of Patients Treated at Verified and Non-Verified Burn Centers in Washington State	EHS	Cancelled
	Matthew Klein — UW / Department of Surgery		
B-083005-H	Validation of Filters to Audit Prehospital Trauma Care	HSQA	Ongoing
	Melissa Schiff — UW / Harborview Injury Prevention & Research Center		

Project Code	Project Title		Program	Status
A-090105-H	Washington State Healthcare Quality Assessment		CFH	Ongoing
	Nguyet Tran	DOH / Community Wellness & Prevention		
A-090205-S	Workforce Training Results		ESA	Cancelled
	Evelyn Hawkins	Workforce Training & Education Coordinating Board		
A-091305-S	The Bereavement Experience for Adults with Cognitive Disabilities following Parent Death		DDD	Cancelled
	Mary Ann Clute	Case Western Reserve University		
B-091405-H	Washington Adult Health Survey		EHS	Ongoing
	Lillian Bensley	DOH / Office of Epidemiology		
A-100305-H	Estimates of Cancer Prevalence in Gulf Veterans Using State Registries		CFH	Ongoing
	Han Kang	Department of Veterans Affairs		
B-100505-S	Spokane County Meth Family Treatment Court Evaluation		CA	Ongoing
	Heidee McMillin	Washington State University		
A-102105-H	Healthy Youth Survey 2006		EHS	Ongoing
	Lillian Bensley	DOH / Office of Epidemiology		
A-102205-S	Determinants of Patient Dropout from Cancer Treatment and Follow-up		MAA	Ongoing
	Scott Ramsey	Fred Hutchinson Cancer Research Center		
A-102305-S	Advance Provision of Female Emergency Contraception in Men Using Condoms for Birth Control: A Pilot Study		ESA	Cancelled
	John Amory	University of Washington		
B-102505-S	Multi-Site Evaluation for Runaway Youth		CA	Completed
	Ernst Stromsdorfer	Rainier Research Associates, LLC		
B-102605-S	Dementia Day Services Evaluation		ADSA	Ongoing
	Rebecca Logsdon	UW / School of Nursing		
C-111405-H	Assessing Confounding in the Application of Serologic Testing Algorithm to Detect Recent HIV Seroconversion (STARHS) in Estimating HIV Seroincidence among Clinical Populations		CFH	Ongoing
	Edward White	UW / Department of Epidemiology		
B-112105-S	The Fourth National Incidence Study of Child Abuse & Neglect		CA	Ongoing
	Andrea Sedlak	Westat (Rockville, Maryland)		
B-112305-H	Previous Pregnancy Outcome and Risk of Breast Cancer		CFH	Ongoing
	Amira El-Bastawissi	DOH / Community and Family Health		
A-121305-S	Workforce Training Results: WorkFirst Participants		ESA	Cancelled
	Evelyn Hawkins	Workforce Training & Education Coordinating Board		

Project Code	Project Title		Program	Status
A-122005-H	Knowledge Base of Breast Cancer Survivors about Lymphedema		CFH	Cancelled
	Valerie Schmidt	University of Puget Sound (student)		
B-122105-S	King County Family Court Study		CA	Completed
	Eric Trupin	UW / Psychiatry & Behavioral Sciences		
A-122905-L	A Pilot Study of Teen's Perspectives about Health & Safety at Work		OTH	Ongoing
	Mary Miller	L&I		
B-010306-S	A Retrospective Evaluation of Colony Stimulating Factor Use in Patients with Breast, Colorectal, and Lung Cancers		MAA	Ongoing
	Scott Ramsey	FHCRC		
B-012406-S	Promoting Infant Mental Health in Foster Care		CA	Ongoing
	Susan Spieker	UW / Family & Child Nursing		
B-013006-H	Population-Based Pediatric Diabetes Epidemiology Studies		EHS	Cancelled
	David Tirschwell	UW / Neurology		
A-013106-L	Evaluating Isocyanate Exposures in Collision Repair Workers		SHAR	Ongoing
	Stephen Whittaker	L&I / SHARP		
A-020106-H	Increasing Awareness of and Knowledge about Prostate Cancer Among African-American Men in Seattle-King County		CFH	Cancelled
	Wendy Nakatsukasa-Ono	Center for MultiCultural Health		
B-020206-S	Using Standardized Defense Attorney Questionnaires in Juvenile Competency Evaluations		MHD	Cancelled
	Dana Jackson			
A-020906-H	Increasing Screening & Follow-Up Rates to Reduce Colon Cancer Incidence & Mortality Among African American Men & Women		CFH	Ongoing
	Wendy Natatsukasa-Ono	Center for Health Training		
A-021606-S	The Evaluation of Community Healthy Marriage Initiatives (CHMI)		ESA	Cancelled
	Anupa Bir	RTI International		
A-022206-H	Seasonal Fluctuations of Asthma Hospitalizations		EHS	Ongoing
	Yolanda Sanchez	UW / Dept. of Environmental & Occupational Health Services		
B-022406-S	Preventing Psychiatric Rehospitalization		MHD	Ongoing
	Robert Short	WSU Spokane		
B-030706-H	Airbags and Pregnancy		EHS	Ongoing
	Melissa Schiff	Harborview Injury Prevention & Research Center		

Project Code	Project Title		Program	Status
A-030806-S	Changes in Bone Mineral Density and Fracture Rate and Incidence at a Residential Habilitation Center after Initiation of Osteoporisis Screening and Management and Falls Prevention Protocols		ADSA	Ongoing
	Kathleen Watson	UW /Biobehavioral Nursing & Health Systems		
B-031506-H	Spokane Colorectal Cancer Screening Program		CFH	Ongoing
	Kathleen Worden	Inland Northwest Health Services		
B-032006-L	Washington Fatality Assessment and Control Evaluation (FACE) Program		SHAR	Ongoing
	David Bonauto	L&I		
A-032306-H	Preparing for a National Trauma Registry for Children (NTRC): Ensuring Data Quality		HSQA	Cancelled
	Karen Guice	Medical College of Wisconsin		
A-032406-H	Surgical Clinical Outcomes Assessment Program		EHS	Ongoing
	David Flum	UW / School of Medicine		
B-041006-S	Drug Treatment Epidemiology in Washington		DASA	Cancelled
	Caleb Banta-Green	University of Washington / Alcohol & Drug Abuse Institute		
B-042406-S	A Qualitative Study of Factors and Behavior Support Programs in Addressing Challenging Behaviors		DDD	Completed
	Christine Rice	Central Washington University / graduate student		
A-042406-S	Mockingbird Family Model Project Evaluation		CA	Cancelled
	Margaret McKenna	UW / Northwest Institute for Children & Families		
B-050506-S	The Use of Poetry Writing in the Self-Expression of Hospitalized Youth		MHD	Ongoing
	Miral Luka	DSHS / Child Study and Treatment Center		
A-051506-S	Bright Start Program Evaluation		ESA	Ongoing
	John Tapogna	ECONorthwest (Portland, OR)		
B-051906-S	Transitioning from ACT to Usual Community Care: Long-term Service Use and Costs		MHD	Cancelled
	Gary Cuddeback	University of North Carolina / Sheps Center		
A-061206-H	PM2.5 and Infant Mortality		EHS	Ongoing
	Jane Koenig	UW / Environmental & Occupational Health Sciences		
A-061806-H	Population-Based Pediatric Diabetes Epidemiology Studies		EHS	Cancelled
	David Tirschwell	UW / Department of Neurology		
B-061906-S	Adolescent Family Life Project Evaluation		CA	Ongoing
	Margaret McKenna	UW / School of Social Work		
B-062106-S	Urologic Issues in Pediatric Condition Falsification		CA	Completed
	Kenneth Feldman	UW School of Medicine		

Project Code	Project Title		Program	Status
A-062106-S	Mockingbird Family Model Project Evaluation		CA	Completed
	Margaret McKenna	UW / School of Social Work		
A-062206-S	TAKE CHARGE Evaluation: A Study of Recently Pregnant Women		MAA	Ongoing
	Laurie Cawthon	DSHS / RDA		

Total Count: 58


WASHINGTON STATE
DEPARTMENT OF
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SERVICES