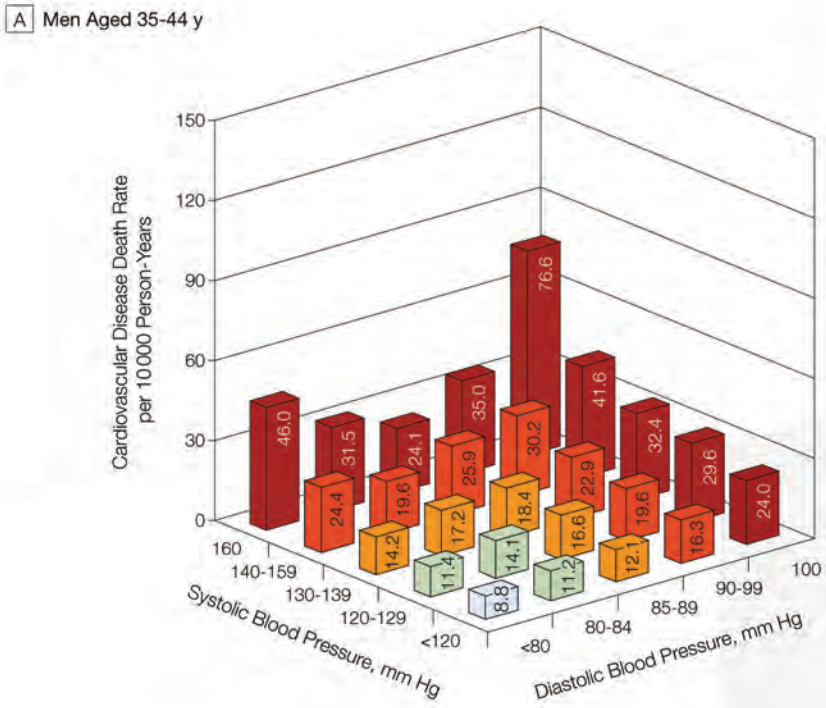

A Men Aged 35-44 y
Cardiovascular Disease Death Rate per 10000 Person-Years
150
120
90
60
30
0
46.0
31.5
24.1
35.0
76.6
24.4
19.6
25.9
30.2
41.6
14.2
17.2
18.4
22.9
32.4
11.4
14.1
16.6
19.6
29.6
8.8
11.2
12.1
16.3
24.0
160
140-159
130-139
120-129
<120
<80
80-84
85-89
90-99
100
Systolic Blood Pressure, mm Hg
Diastolic Blood Pressure, mm Hg

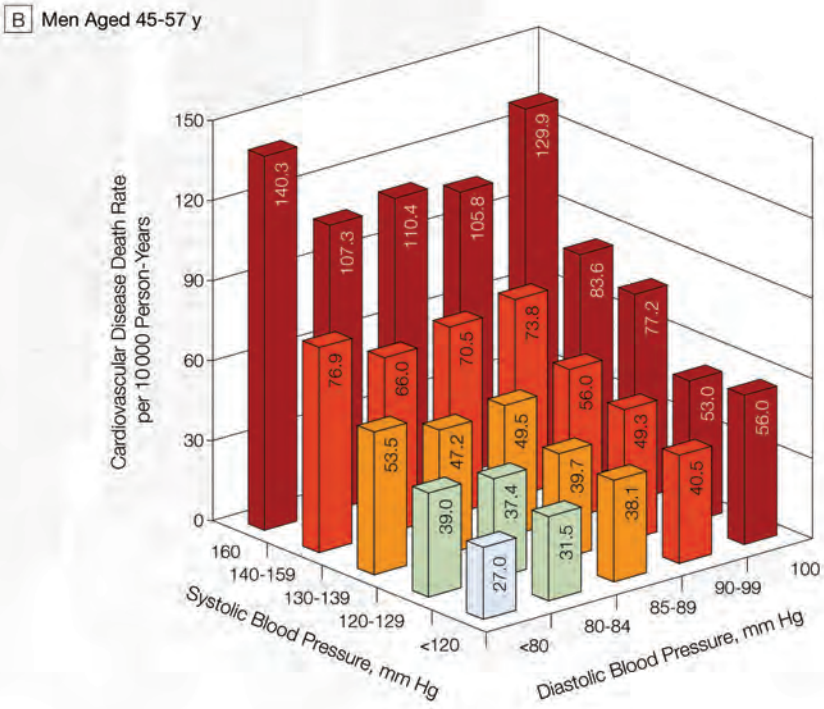

B Men Aged 45-57 y
Cardiovascular Disease Death Rate per 10000 Person-Years
150
120
90
60
30
0
140.3
107.3
110.4
105.8
129.9
76.9
66.0
70.5
73.8
83.6
53.5
47.2
49.5
56.0
77.2
39.0
37.4
39.7
49.3
53.0
27.0
31.5
38.1
40.5
56.0
160
140-159
130-139
120-129
<120
<80
80-84
85-89
90-99
100
Systolic Blood Pressure, mm Hg
Diastolic Blood Pressure, mm Hg

Table of Contents

Dear Alumni, Students, Colleagues, and Friends of the Division of Biostatistics,

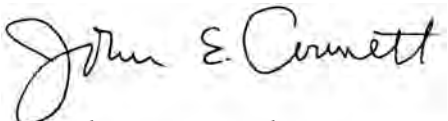
Another incredibly productive year for the Division of Biostatistics – here are some of the notable events (with additional details later in this report):

- Two of our PhD students received a 2007 Distinguished Student Paper Awards at the ENAR Spring meeting in Tampa, Florida.
- Wei Pan was promoted to the rank of Full Professor, and Sudipto Banerjee and Cavan Reilly were promoted to Associate Professor with tenure, all approved at the June 2007 meeting of the University's Board of Regents.
- The Division, in conjunction with the Academic Health Center's Office of Clinical Research (OCR), continues to search for qualified staff for the OCR's Biostatistical Design and Analysis Center (BDAC). In February 2007, Hongfei Guo, a recent graduate of Johns Hopkins University, was appointed Assistant Professor in the Division, with 80% of his support coming from the BDAC.
- Division faculty, staff and students were primary authors or co-authors of over 200 research publications, and had substantive involvement as investigators in 73 collaborative projects. This is an astonishing level of productivity.

It is with deep regret that I must report the passing of former Division Head Marc Kjelsberg. There is a brief biography included later in this report. In recognition of Marc's great contributions to clinical trials research and his excellent steady leadership in the Division and the School over a 30-year period, we are establishing a student award fund in his honor. Contributions are welcome!

We have now appointed 3 faculty from the Mayo Clinic Division of Biostatistics as adjunct faculty within our Division: Dan Sargent, Karla Ballman, and Jeff Sloan. This is the beginning of a very promising research, advising, and teaching collaborative arrangement with Mayo. We are working on a plan to offer the MS in Biostatistics to Mayo staff and others through the new facilities at the University of Minnesota in Rochester.

There are plenty of challenges ahead for the next year. The Division is heavily involved in the application for the NIH-sponsored Clinical and Translational Science Award (CTSA), which we hope will be granted in 2008. The demand for biostatisticians, especially those with interests in clinical trials and other aspects of clinical research, is sharply increasing. At the present time we are involved in 5 open searches for additional faculty and staff at the PhD level, and there is a lot of competition. Wish us luck!



John E. Connett, PhD
Professor and Head
Division of Biostatistics, School of Public Health

The Division of Biostatistics and the School of Public Health Mourns the death of Marcus Kjelsberg

Marcus Olaf Kjelsberg was born on December 27, 1932 in Mayville, North Dakota. His elementary school training was in a rural one-room in North Dakota. Although he himself never mentioned it, he was somewhat of a prodigy, entering Concordia College in Moorhead, Minnesota at the age of 16, with interests encompassing mathematics, music, and theatrics. Marc graduated from Concordia College in 1952, with a bachelor's degree in mathematics. He became a graduate student in Statistics at the University of Minnesota, earning his Master's in 1955. He was an Instructor in Biostatistics at Tulane University, 1957-1960, and returned to Minnesota in 1960 to earn his PhD in Biostatistics (1962), under the mentorship of Dr. Eugene Johnson. He served as Assistant Professor of Biostatistics at the University of Michigan, 1961-1966. In September, 1966, he returned to Minnesota as Associate Professor of the Division of Biometry [the Division was originally named Biostatistics, but was titled Biometry from 1964 to 1987, when it reverted to being Biostatistics].

Marc was appointed Division Head in 1972, and served in this position until 1987. He was promoted to the rank of Professor in 1975. He was appointed Associate Dean for Administration in 1994. Marc retired from the faculty in 1997. He continued to serve after his retirement as Associate Editor of Controlled Clinical Trials and as a member of the Editorial Committee for the Multiple Risk Factor Intervention Trial (MRFIT).

Possibly Marc's most important accomplishment and enduring legacy grew out of the MRFIT. Marc became Principal Investigator for the Data Coordinating Center of the MRFIT in 1972. The MRFIT, sponsored by the National Heart, Lung and Blood Institute, was a large, complex enterprise: over 361,000 men were screened for this study, with ultimately 12,866 randomized in 22 clinical centers located around the U.S. The objective was to determine whether intervention aimed at reducing blood pressure and serum cholesterol and achieving cessation of smoking could reduce the rate of coronary heart disease death in men 35 to 57 years of age. The MRFIT was near the cutting edge in the use of number of technologies in clinical trials, including the large-scale use of computers, distributed data collection, comprehensive data management, centralized laboratory facilities, and elaborate data quality control. The primary findings of the MRFIT were published in the Journal of the American Medical Association in April, 1982. Although authorship of this paper was listed as 'the MRFIT Research Group' and listed a cast of thousands in its Acknowledgements, Marc Kjelsberg was one of the primary contributors to the manuscript. Remarkably, because this paper was so carefully and well-written and because the MRFIT was carried out in such an exemplary manner, the paper was republished by JAMA in February, 1997. Research on the cohorts of MRFIT screenees and trial participants continues up to the present time, making use of mortality records from the Social Security Administration and the National Death Index and over 15,000 serum samples which were collected at baseline screening visits in the MRFIT.

Over time, the MRFIT Data Coordinating Center, which included about 60 employees at the height of its operation, spawned data and statistical coordinating centers for other clinical trials, including the Diabetic Retinopathy Vitrectomy Study, the Mild Hypertension Study, the Granulocyte Transfusion Study, the Lung Health Study (for which Marc Kjelsberg was the initial Principal Investigator), the Community Program for Clinical Research in AIDS, and a number of others. At the present time, the Division is the home of the Coordinating Centers for the COPD Clinical Research Network (COPD-CRN) and for the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT). These studies are part of the Coordinating Centers for Biometric Research (CCBR). The CCBR, with its tradition of sound statistical design, obsessive data quality control, and rigorous data analysis, is really the major enduring legacy of Marc Kjelsberg's work in clinical trials.

Marc Kjelsberg died on July 11, 2007, as a result of complications of leukemia. He is survived by his wife, Marge, his son Michael, and his daughter, Ann. Marc was universally known as an insightful researcher and teacher, a man of principle who was absolutely dedicated to the University, the School of Public Health, and the Division of Biostatistics, and a gentle and modest man with a streak of humor and irony. He will be greatly missed by all who knew him.

The Division of Biostatistics is establishing a student award fund in Marc's honor. This will be similar to the award funds generously initiated by the late Professor Jacob E. (Pete) Bearman (the Bearman Award) and by Professor Emeritus James Boen (the Boen Award). The Marcus O. Kjelsberg Clinical Trials Award will given annually to the best student working in the area of clinical trials, whether as a Research Assistant, a Trainee in Clinical Trials, or for a Plan B or a PhD dissertation related to clinical trials. We welcome contributions to this new fund, which will be managed by the Minnesota Medical Foundation.

Significant Events of 2006-2007

Sudipto Banerjee, Assistant Professor, was promoted to Associate Professor with tenure on June 11, 2007.

Brad Carlin, Professor, became Editor of Bayesian Analysis, the official journal of the International Society for Bayesian Analysis (ISBA) as of January 1, 2007.

John Connett, Professor and Division Head, won the Leonard M. Schuman Excellence in Teaching Award presented by the University of Minnesota and the School of Public Health in Jun e2007. This award is given to a full-time School of Public Health faculty who has demonstrated excellence in the classroom for five or more years.

The Division of Biostatistics offered one course during the 2007 School of Public Health Institute. This was the third year the Division of Biostatistics participated. The SPH Institute provides professionals the opportunity to immerse themselves in a chosen field of study - for a single course or for the entire three weeks of the Institute. The course offered this year was: "Introductory Biostatistics for Healthcare Professionals" co-instructed by **Cynthia Davey,** Associate Director, Biostatistics Consulting Laboratory.

Lynn Eberly, Associate Professor, spent the 2006-2007 academic year on sabbatical as a Visiting Scholar, Department of Biostatistics, Bloomberg School of Public Health, Johns Hopkins University, working with Dr. Brian Caffo on statistical issues in medical imaging.

Patricia Grambsch, Associate Professor, is on sabbatical at Cambridge University, January 1 – December 31, 2007.

Hongfei Guo, Assistant Professor, was appointed assistant professor in the Division of Biostatistics and joined the Division in February 2007. Dr. Guo earned his Ph.D. in Biostatistics from Johns Hopkins University. He is particularly interested in multivariate data analysis, statistical methods and analysis for longitudinal data and survival data, design and analysis of clinical trials, and application of Bayes methods to clinical research. Dr. Guo's primary work is in the Biostatistics Design and Analysis Center in the AHC's Office of Clinical Research.

The American Academy of Periodontology awarded its 2007 Clinical Research Award to the OPT Study Group for their paper in the New England Journal of Medicine: Michalowicz BS, **Jim Hodges,** DiAngelis AJ, Lupo VR, Novak MJ, Ferguson JE, Buchanan W, Bofill J, Papapanou PN, Mitchell DA, Matseoane S, Tschida PA. "Periodontal Treatment and Risk of Preterm Birth: Results from the OPT Trial." New England. Journal of Medicine, 355:1885-1894, 2006.

Brent Johnson (MS, University of Minnesota, 1997; PhD, North Carolina State, 2005) was appointed as Assistant Professor (Tenure track) of Biostatistics at Emory University. Started appointment in July 2006.

Doctoral students **Shengde Liang** and **Luping Zhao** each received a 2007 ENAR Distinguished Student Paper Award. They presented their work at the 2007 ENAR spring meeting in Tampa, Florida.

James Neaton, Professor, served as president of the Society for Clinical Trials from May 2006 until May 2007.

Wei Pan, Associate Professor, was promoted to Full Professor on June 11, 2007.

Cavan Reilly, Assistant Professor, was promoted to Associate Professor with tenure on June 11, 2007.

Daniel Sargent (PhD, 1996) was named to the National Cancer Institute's newly formed Clinical Trials Advisory Committee. This committee is the first new NCI advisory committee in over 10 years and is charged with overseeing the entire NCI clinical trials portfolio.

Joanna Shih (PhD, 1992) was elected as a 2007 American Statistical Association Associate fellow.

Jia Xu (Biostatistics student), **Timothy Hanson** (Associate Professor), and **Dongfeng Qi** (Biostatistics Alumnus, Medtronic) were honored in May as new members of Delta Omega. Delta Omega is an honorary society for graduate studies in public health. Delta Omega celebrates excellent academic achievement, devotion to public health principles, and outstanding service in public health.

In May the School of Public Health recognized its Civil Service/Bargaining Unit employees. Among those recognized were 5 Biostatistics employees: **Igor Garivodsky** (5 years), **Peter Laudert** (10 years), **Siu-Fun Quan** (15 years), **Anita Carter** (20 years), **Nanci Hurlbut** (20 years), **Cindy Miller** (30 years), **Mary Lou Rapacz** (30 years).

The Biostatistics AIDS Walk team raised a little over $12,000 for HIV/AIDS research, ranking them 2nd out of the hundreds of teams that entered the 2007 Minnesota AIDS Walk. Funds raised were entirely private donations. This is the fourth year the Biostatistics team's fundraising placed in the top ten.

It is with deep regret that we must report the death of Marc Kjelsberg on July 11, 2007. Marc had a long and very distinguished career in this Division as a faculty member, Division Head, and Associate Dean. Included in this report is a brief biography of this remarkable man, distinguished colleague, and cherished friend.

2006-2007 Biostatistics at a Glance

The Division of Biostatistics involves well over 100 people, in all aspects of its teaching, research and outreach mission.

Academic Administration
Megan Adamson
Julie Dobbs
Ruth Goerger
Sally Olander
Desdamona Racheli

Divisional Administration
Abby Bendickson
Janet Bendickson
River Berens
Kathryn Brillhart
Cindy Miller
Bill Norman
Bradley Rapacz
Kate Schmidt
Linda Zenner

Faculty
Sudipto Banerjee
Saonli Basu
Tracy Bergemann
Bradley Carlin
John Connett
Lynn Eberly
Anne Goldman
Patricia Grambsch
Hongfei Guo
Tim Hanson
Jim Hodges
Chap Le
Na Li
Xianghua Luo
Andy Mugglin
James Neaton
Wei Pan
Cavan Reilly
Susan Telke
Will Thomas
Melanie Wall
Baolin Wu

Adjunct Faculty
Sue Duval
David Nelson
Judy Punyko
Daniel Sargent

Non-Biostatistics Faculty
Birgit Grund
Alan Lifson
Christine Wendt

Non-Biostatistics Support Staff
Andrew Finley
Jennifer Hall
Deann Lazovich
Amy Lynch
Wei Tang

Sr. Research Associates
Dorothee Aeppli

Research Associates
Katherine Huppler Hullsiek
Rob Leduc

Sr. Research Fellows
Lisa Fosdick
Greg Grandits
Grace Peng
Debby Wentworth

Research Fellows
Gary Collins
Cynthia Davey
Eileen Denning
Ann Fieberg
Sarah Harnden
Kathy Herman-Lamin
Carol Miller
Jacqueline Neuhaus
William Patrek
Mollie Roediger
Pat Tschida
Avis Thomas
Nicole Wyman

Projects Support Staff
Zarina Alloo
Patty Bollenbeck
Anita Carter
Vanna Dinh
Kathy Farnell
Luann Grembowski
Leslie Klemme
Judy Hobrough
Nanci Hurlbut
Eric Krum
Gregg Larson
Peter Laudert
Phyllis Layland
Marrine McMillian
Sue Meger
Candy Nelson
Ray Nelson
Irene Olson
Mary Rapacz

Technical Projects Support Staff
Glenn Bartsch
Glenn Davis
Alain DuChene
Gina Ganab
Michelle George
Igor Gorivodsky
Merrie Harrison
Andy Nguyen
Joyce Ong
Kien Quan
Siu-Fun Quan
Terri Schultz
Gregory Thompson
Helen Voelker
Hua Yu

Academics

Degrees Granted 2006-2007

Doctor of Philosophy (PhD)

Freda Cooner, *Latent Activation Cure Rate Modeling for Time-To-Event Data,*
Advisor: Sudipto Banerjee and Bradley Carlin

Jia Guo, *Biostatistical Models with Latent Variables*
Advisor: Melanie Wall

Yi He, *Bayesian Analysis of Real-Time RT-PCR Data with Right Censoring*
Advisor: Jim Hodges

Haijun Ma, *Bayesian Hierarchical Boundary Analysis for Areal Public Health Data*
Advisor: Bradley Carlin

Guanghua Xiao, *Integrating Biological Knowledge and Other Sources of Data into Microarray Data Analysis*
Advisor: Wei Pan

Yang Xie, *Integrated Analysis of Genomic Data to Study Gene Regulation*
Advisor: Wei Pan and Arkady Khodursky

Yan Zheng, *Topics in the Low-level Analysis of Microarrays*
Advisor: Cavan Reilly and Wei Pan

Master of Science, (MS)

Qing Cao
Colleen Curran
Hong Ge
Adele Golden
Tarek Haddad
Brian Hobbs
Shengde Liang
Yi Peng
James Pottala
Nicholas Salkowski
Shweta Sharma
Hua Tian
Dan Wang
Peng Wei
Na Yuan

Master of Public Health (MPH)

Vaughn Barry

Academics

2006-2007 Student Awards

Jacob E. Bearman Student Achievement Award
The Bearman Award, presented annually in recognition of outstanding academic and professional achievement, is given in honor of Jacob "Pete" Bearman. Dr. Bearman was a faculty member in the Division from 1953 to 1978 and headed the Division from 1956 to 1965. Dr. Bearman passed away in 2005. The 2006-2007 recipient was:

Yue Cui

Yue received BS and MS degrees from Nanjing University in Computational Mathematics and has an MS degree in Biostatistics from the University of Minnesota. Yue plans to complete a PhD in Biostatistics at the University of Minnesota in 2008.

James R. Boen Graduate Award
The James R. Boen Graduate Award was established in 2000 in honor of retired Biostatistics Professor James R. Boen. This award recognizes biostatistics students whose achievements are strongest in applied biostatistics. The 2006-2007 recipient was:

Brian Hobbs

Brian received a Bachelor of Arts degree in Anthropology with a minor in Computer science from University of Iowa. In 2007, Brian received an MS in Biostatistics from the University of Minnesota. Currently, Brian is in University of Minnesota PhD program in Biostatistics.

Biostatistics Research Assistant Award
The Division established a Research Assistant Award during the 2005-2006 academic year. The award recognizes outstanding work as a research assistant and acknowledges contribution to the Division's statistical methods and collaborative research mission. The 2006-2007 recipients were:

Xiaoxiao Kong
Zhenyu Pan
Nicholas Salkowski
Qun Shi

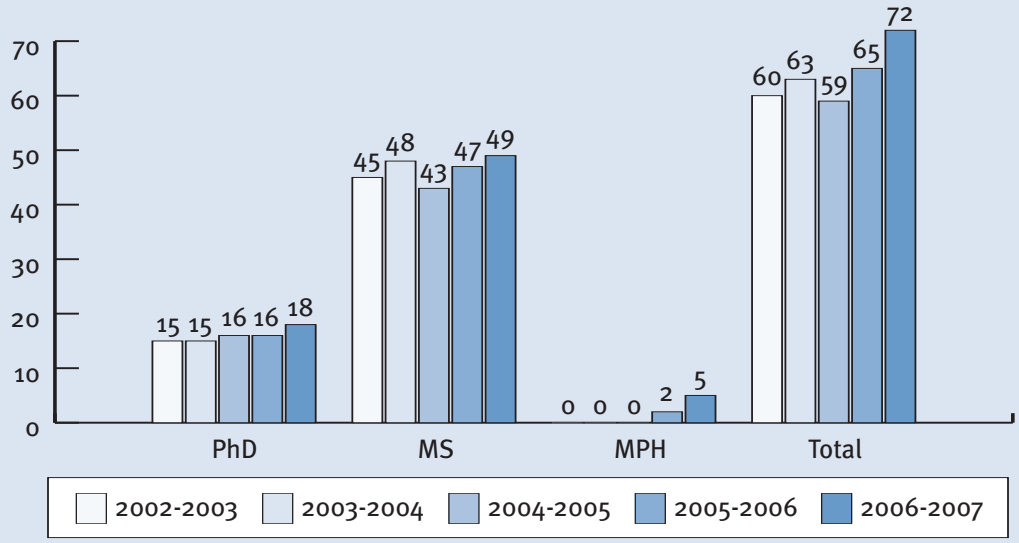
Biostatistics Teaching Assistant Award
The Division established a Teaching Assistant Award during the 1997-1998 academic year. The award recognizes outstanding service as a teaching assistant and acknowledges contributions to the Division's educational mission. The 2006-2007 recipients were:

An Liu
Katie Schomaker
Milan Seth
Luping Zhao

We thank our alumni and friends of the Division for their generous support of the Jacob E. Bearman Student Achievement Award and the James R. Boen Graduate Fund. We invite contributions for the Marcus O. Kjelsberg Clinical Trials Award. Please contact the Minnesota Medical Foundation (www.mmf.umn.edu) for more information.

Academics

Student Enrollment in Biostatistics Past Five Academic Years



Active Students 2006-2007

MPH

Brunna Alves
Christopher Anderson
Vincent Mendy
Stacia Merkel
Kristen Ward

MS

Zhihua Bian
Carlye Borth
Ann Brearley
Haowen Cai
Timothy Connors
Colleen Curran
Daniel Dvorkin
Juanran Feng
Hong Ge
Hua He
Wei He
Qinlei Huang
Zhi Huang
Rachel Isaksson
Jonathan Johnson
Wenjun Kang
Xiaoxiao Kong
SangMee Lee
Pei Li
Ran Li
Xiang Li
Haiying Lin
Fang Liu
Jianmin Liu
Xiao Liu
Xiaobo Liu
Minghui Lu
Zhenyu Pan
Yi Peng
James Pottala
Ying Qi
Joshua Rapkin
Nicholas Salkowski
Esther (Katie) Schomaker
Milan Seth
Qun Shi
Hua Tian
Dan Wang
Qi Wang
Melissa Warden
Nicholas Wold
Min Xi
Jia Xu
Jiaqi Yang
Qingqing Yang
Zhuolun Yao
Li Yuan
Na Yuan
Xinyu Zhou

PhD

Yue Cui
Tianming Gao
Jia Guo
Tarek Haddad
Yi He
Brian Hobbs
Meijuan Li
Shengde Liang
Haiying Lin
An Liu
Cristina Oancea
Stefanie Schussler
Feng Tai
Peng Wei
Benhuai Xie
Yufen Zhang
Luping Zhao
Yanni Zhu

Graduate Faculty

Sudipto Banerjee

Associate Professor of Biostatistics

M.S., 1996, Statistics, Indian Statistical Institute, Calcutta, India
Ph.D., 2000, Statistics, University of Connecticut

Sudipto Banerjee joined the Division of Biostatistics in the Fall of 2000. His research interests include modeling spatial data with emphasis on prediction, interpolation and regression methods for misaligned datasets. He is also involved in developing methods for inferring about rates of change on spatial surfaces. Sudipto has also been applying statistical methods to spatially referenced survival data.

Saonli Basu

Assistant Professor of Biostatistics

M.S., 1998, Statistics, Indian Statistical Institute, Calcutta, India
Ph.D., 2005, Statistics, University of Washington

Saonli Basu's research interests include stochastic modeling, statistical genetics, computational statistics, MCMC. She is particularly interested in developing statistical methods and software tools for linkage and association studies for complex traits. She is actively involved in few genome-wide association studies. She also has collaborations with applied projects within the dental school.

Tracy L. Bergemann

Research Associate, University of Minnesota Cancer Center

MS, 1999, Biostatistics, University of Washington
Ph.D., 2004, Biostatistics, University of Washington

Tracy Bergemann researches image analysis of microarray data, methods to describe signal quality from cDNA microarrays, methods for analysis of microarray data, haplotype modeling for genetic epidemiology studies, and more generally, bioinformatics, statistical genetics, and genetic epidemiology. She is a member of the Cancer Center with a focus on the genetic mechanisms of cancer and cancer epidemiology.

Bradley P. Carlin

Professor of Biostatistics

M.S., 1986, Statistics, University of Connecticut
Ph.D., 1989, Statistics, University of Connecticut

Brad Carlin's teaching experience and interests include introductory probability and statistics, statistical computing, and graduate level methodology and data analysis courses. His research deals primarily with the development of Bayes and empirical Bayes methodology for biostatistical problems, and the development and analysis of Markov chain Monte Carlo computational techniques for implementing these methods. His applied interests include statistical applications in cancer control, spatio-temporal disease mapping, clinical trials, and sports statistics.

Graduate Faculty

John E. Connett

Professor of Biostatistics
Division Head
A.B., 1963, A.M., 1964, Mathematics, University of Missouri
Ph.D., 1969, Mathematics, University of Maryland

John Connett has research interests in clinical trials in lung disease, ophthalmology and cardiovascular disease, case-control studies, estimation of odds ratio, random effects and longitudinal models, coefficient-of-variation models for laboratory data, variance estimation, and statistical computing.

Susan Duval

Assistant Professor of Epidemiology and Community Health
Ph.D., 1999, Biostatistics, University of Colorado Health Sciences Center

Statistical methods in epidemiology, meta-analysis methodology and related applications, publication bias, statistical consulting, cardiovascular, and diabetes epidemiology.

Lynn E. Eberly

Associate Professor of Biostatistics
M.S., 1994, Statistics, Cornell University
Ph.D., 1997, Statistics, Cornell University
SPH Leonard M. Schuman Award for Excellence in Teaching

Lynn Eberly's current research interests involve methods for correlated data including time-to-event, clustered, and longitudinal data. She holds particular interest in clinical/ intervention trials, environmental exposure studies, pharmaco-epidemiology, and related applications. She was on sabbatical during 2006-2007 as a Visiting Scholar at Johns Hopkins University to learn about statistical issues in medical imaging such as MRI, fMRI, and spectroscopy. Lynn is Director of the Multiple Risk Factor Intervention Trial (MRFIT) Coordinating Center. She is Co-Investigator on the project Outcomes Associated with AED Use by Elderly, and Biostatistician on the project MRS and MRI of Breast Cancer at Very High Magnetic Field. She teaches courses on methods for correlated data as well as on regression, ANOVA, and experimental design.

Patricia M. Grambsch

Associate Professor of Biostatistics
Ph.D., 1980, Statistics, University of Minnesota

Patricia Grambsch has research experience at the Mayo Clinic and Bell Labs. Her research interests include mathematical modeling of biological phenomena, survival analysis with emphasis on counting process approaches and diagnostics, sequential analysis, crime statistics and infectious diseases.

Graduate Faculty

Birgit Grund

Associate Professor of Statistics

M.S., 1982, Math/Statistics, Humboldt-Universität (Berlin)
Ph.D., 1987, Math/Statistics, Humboldt-Universität (Berlin)

Birgit Grund has research interests in nonparametric curve estimation, smoothing methods, clinical trials and AIDS research.

Timothy E. Hanson

Associate Professor of Biostatistics

M.A., 1996, Mathematics, University of New Mexico
M.S., 1998, Statistics, University of California at Davis
Ph.D., 2000, Statistics, University of California at Davis

Tim Hanson joined the Division of Biostatistics in fall of 2005 after five years on the faculty at the University of New Mexico. Tim Hanson's research interests include developing methods for analyzing survival data with time dependent covariates, including extensions of proportional hazards, proportional odds, and accelerated failure time models. Tim is also interested in developing models for measuring diagnostic test accuracy and disease assessment. Tools used in his research include Bayesian nonparametric methods and associated MCMC methodology. Tim has taught a wide variety of courses including regression, experimental design, survival analysis, Bayesian statistics, data analysis, probability, and statistical inference.

James S. Hodges

Associate Professor of Biostatistics

M.A., 1986, Public Affairs, University of Minnesota
Ph.D., 1985, Statistics, University of Minnesota

Jim collaborates with researchers at the Center for Chronic Disease Outcomes Research (CCDOR) at the Minneapolis Veterans' Affairs Medical Center, and at the Minneapolis Heart Institute Foundation, and with various investigators in the University's Academic Health Center. Over the years he has worked with researchers in dentistry, AIDS, gastroenterology, demographics, wildlife management, ornithology, horticulture, combat analysis, military logistics, simulation models, airport safety, and marketing. His statistical research is in hierarchical and other richly-parameterized models.

Katherine Huppler Hullsiek

Research Associate

M.S., 1989, Mathematics, St. Cloud State University
M.S., 1996, Biostatistics, University of Minnesota
Ph.D., 1999, Biostatistics, University of Minnesota

Kathy Huppler Hullsiek has research interests in AIDS and other infectious disease research. She works as a statistician for INSIGHT, an international HIV clinical trials network, and is a co-investigator for the Infectious Disease Clinical Research Program (IDCRP) data analysis center.

Graduate Faculty

Chap T. Le

Distinguished Professor of Biostatistics
Director of Biostatistics - Comprehensive Cancer Center
M.A., 1971, Mathematics, California State University - Fresno
Ph.D., 1978, Statistics, University of New Mexico

Dr. Le teaches PubH 7405 (Biostatistics Regression) in the Fall semester and PubH 7470 (Biostatistics for Translational and Clinical Research) in the Spring semester. His collaboration has focused on analyses of survival and categorical data from clinical and translational research projects. His methodological research interests include epidemiological methods, crossover designs, survival analysis, logistic regression, correlated binary data, ordered alternatives, ROC curves, and, recently, the design and analysis of *in vitro* experiments for studying cancer drugs - especially, chemocombination therapy.

Dr. Le is the author of the textbooks: *Fundamentals of Biostatistical Inference (1992), Health and Numbers (1995, 2001, and 2008-in press), Applied Survival Analysis (1997), Applied Categorical Data Analysis/ (1998), and Introductory Biostatistics (2003), and Statistics Quick Reference Guide (2007-in press).*

Robert E. Leduc

Research Associate
Ph.D., 1994, Mathematics, University of Wisconsin - Madison

Robert Leduc's research interests include clinical trials, especially in HIV research and kidney transplantation. Robert also has an interest in problems related to missing data or losses to follow-up, and drug resistance issues.

Na (Michael) Li

Assistant Professor
M.S., 1998, Biochemistry, Peking University
M.S., 2000, Biostatistics, University of Washington
Ph.D., 2003, Biostatistics, University of Washington

Na (Michael) Li's research interests include statistical genetics, bioinformatics, stochastic processes and statistical computing.

Xianghua Luo

Assistant Professor of Biostatistics
M.S., 2000, Quaternary Geology, Peking University
Ph.D., 2006, Biostatistics, Johns Hopkins University

Xianghua Luo's research interests include nonparametric and semiparametric methods for recurrent event survival data, informative censoring, and case-crossover design. Collaborations include cancer research, bone marrow transplant (BMT), smoking cessation, gerontology, and pediatric psychiatry.

Andy Mugglin

Research Associate Professor of Biostatistics
Ph.D., 1999, Biostatistics, University of Minnesota

Andy Mugglin's research interests include Clinical trials, especially in cardiovascular medical device applications; Bayesian and other innovative clinical trials design; Bayesian hierarchical modeling, spatio-temporal modeling, and computing.

Graduate Faculty

James D. Neaton

Professor of Biostatistics
Director of Community Programs for Clinical Research on AIDS - Statistical Center
M.S., 1970, Biometry, University of Minnesota
Ph.D., 1984, Biometry, University of Minnesota

Jim Neaton's research interests are in the design and conduct of clinical trials. He currently is the leader of a large international clinical trials network called INSIGHT that is studying treatments for HIV. He is also actively involved in trials of heart failure and epidemiological studies of risk factors for cardiovascular disease. He serves on a number of data monitoring committees and advisory groups to the National Institutes of Health. He is Past-President of the Society for Clinical Trials. He teaches a course on the design and implementation of clinical trials.

David Nelson

Assistant Professor of Medicine
Senior Statistician, Center for Chronic Disease Outcomes Research
Minneapolis VA Medical Center
M.S., 1994, Statistics, University of Minnesota
Ph.D., 1998, Statistics, University of Minnesota

David Nelson is developing methods for inference in observational studies and model diagnostics using sufficiency and propensity theory. He also is interested in stepwise Bayes methods for infinite population sampling and nonparametric statistical analysis.

Wei Pan

Associate Professor of Biostatistics
M.S., 1995, Computer Science, University of Wisconsin, Madison
M.S., 1996, Statistics, University of Wisconsin, Madison
Ph.D., 1997, Statistics, University of Wisconsin, Madison

Wei Pan has research interests in bioinformatics, machine learning and data mining, survival analysis, and analysis of correlated/longitudinal data. He has taught courses on survival analysis, categorical data analysis, linear models and generalized linear models, microarray data analysis, statistical learning and data mining. Wei is associate editor for the Journal of the American Statistical Association and for Statistics in Medicine.

Judy Punyko

Adjunct Assistant Professor, Epidemiology and Community Health
M.S., 1990, Biostatistics, University of Minnesota
Ph.D., 2004, Epidemiology, University of Minnesota

Judy Punyko's interests include statistical consulting in public health, maternal and child health, and epidemiology, biostatistics education for non-majors, developing QA/QC programs for disease surveillance systems, bias in epidemiologic research, and chronic disease epidemiology in adult and pediatric populations.

Cavan Reilly

Assistant Professor of Biostatistics
M.A., 1995, Economics, New School for Social Research
M.A., 1996, Statistics, Columbia University
Ph.D., 2000, Statistics, Columbia University

Cavan Reilly has research interests in applied stochastic processes, statistical genetics/genomics/proteomics and Bayesian statistics. Most of his applied work is with AIDS/HIV.

Graduate Faculty

Daniel Sargent

Adjunct Professor of Biostatistics
Director, Cancer Center Statistics, Mayo Clinic Cancer Center
M.S., 1994, Biostatistics, University of Minnesota
Ph.D., 1996, Biostatistics, University of Minnesota

Daniel J. Sargent, Ph.D., is the Group Statistician for the North Central Cancer Treatment Group, an NCI supported Cancer Cooperative Group, and the director of Cancer Center Statistics at the Mayo Clinic Comprehensive Cancer Center. He has been the lead statistician for the Gastrointestinal Cancer Research at the Mayo Clinic Cancer Center since 1995. He is recognized as a national leader in the statistical aspects of cancer. Dr. Sargent has a strong record of statistical methodological development, including the area of clinical trial design. He has published papers on innovative designs for Phase I, II, and III clinical trials. Other published methodological areas of interest include survival analysis, meta-analysis, surrogate endpoints, and statistical computing.

William Thomas

Associate Professor of Biostatistics
Director of Statistics and Computing, General Clinical Research Center
M.S., 1982, Statistics, University of Minnesota
Ph.D., 1987, Statistics, University of Minnesota

Will Thomas' interests include clinical research and statistics education, with research in statistical diagnostics, longitudinal data, error-in-variables and variance estimation.

Melanie M. Wall

Associate Professor of Biostatistics
Director of Graduate Studies
M.S., 1995, Statistics, Iowa State University
Ph.D., 1998, Statistics, Iowa State University

Melanie Wall's interests include latent variable and structural equation modeling, spatial data analysis, and longitudinal data analysis. She has applied these statistical methodologies in several areas including: determining factors influencing eating behaviors in adolescents, alcohol rehabilitation clinic assessment, mapping disease rates, and improving Department of Health statistics.

Baolin Wu

Assistant Professor of Biostatistics
B.S., 1999, Probability and Statistics, Peking University
Ph.D., 2004, Biostatistics, Yale University

Baolin Wu is interested in developing statistical and computational tools to help solve scientific problems in molecular biology and genetics. Currently his focuses are on the following areas: computational biology, proteomics, statistical genetics, multiple hypothesis testing, and machine learning.

Instructors

Cynthia Davey

Sr. Research Fellow, Biostatistical Design and Analysis

M.S., 1998, Biostatistics, University of Minnesota

Cynthia Davey is a statistical consultant with the Biostatistical Design and Analysis Center in the Office of Clinical Research. As a consultant she has the opportunity to work on a variety of public health and clinical studies. Currently she is a collaborator in research projects focused on adolescent obesity, otitis media (ear infections), ALS and Multiple Sclerosis.

Greg Grandits

Senior Research Fellow

M.S., 1982, Statistics, University of Minnesota

Greg Grandits's research interests include design and analysis of clinical trials, survival analysis, and developing sofware tools in SAS for statistical report generation and other applications. He teaches a introduction to SAS programming class, both an in-class and an online version.

Susan Telke

Instructor

M.S., 1998, Biostatistics, University of Minnesota

Susan Telke teaches several Biostatistical cores courses including PubH 6414-6415 (Biostatistical Methods I and II) as well as PubH 6450. She developed an online method of instruction for PUbH 6415 that was implemented in Summer 2007. She holds a B.S. degree in Art for the University of Wisconsin at Madison and a M.S. degree in Biostatistics from the University of Minnesota Twin Cities.

Courses

The following is a list of Biostatistics courses currently offered by the Division of Biostatistics. Those courses marked with an * were not taught during the 2006-2007 academic year.

Courses for Non-Biostatistics Majors

HSEM 3010H, ***Introduction to Randomized Clinical Trials***
(2 cr, spring, n=15) Connett
PubH 6414, ***Biostatistical Methods I***
(3 cr, fall, n=130) Telke/Davey;
(3 cr, spring, n=36) Davey,
(3 cr, summer, n=76) Davey
PubH 6415, ***Biostatistical Methods II***
(3 cr, spring, n=19) Telke,
(3 cr, summer, n=24) Telke
PubH 6420, ***Statistical Computing I - Using Statistical Packages***
(1 cr, fall, n=50) Grandits,
(1 cr, summer, n=26) Grandits
PubH 6450, ***Biostatistics I***
(4 cr, fall, n=147) Carlin/Telke,
(4 cr, spring, n=29) Basu
PubH 6451, ***Biostatistics II***
(4 cr, spring, n=121) Thomas
PubH 6460, ***Introduction to Biostatistical Thinking***
(1 cr) *
PubH 6470, ***SAS Procedures and Data Analysis***
(3 cr, spring, n=31) Thomas

Biostatistics M.S./M.P.H. Courses

PubH 7400, ***Topics in Biostatistics: Fundamentals of Biostatistical Inference*** (4cr, Fall, n=16) Hanson
PubH 7400, ***Topics in Biostatistics: Biostatistics Modeling & Methods***
(4 cr, spring, n=13) Bergemann
PubH 7400, ***Topics in Biostatistics: Statistics for Translational & Clinical Research*** (3 cr, spring, n=7) Le
PubH 7405, Biostatistics Regression
(4 cr, fall, n=25) Wu
PubH 7406, ***Biostatistics Design and ANOVA***
(4 cr, spring, n=21) Bergemann
PubH 7407, ***Analysis of Categorical Data*** (3 cr, spring, n=31) Hanson
PubH 7420, ***Clinical Trials*** (3 cr, spring, n=74) Neaton
PubH 7430, ***Statistical Methods for Correlated Data*** (3 cr, fall, n=30) Li
PubH 7435, ***Latent Variable Models***
(3 cr, fall, n=19) Wall
PubH 7440, ***Introduction to Bayesian Analysis***
(3 cr, spring, n=15) Banerjee
PubH 7445, ***Statistics in Genetics & Molecular Biology*** (3 cr, spring, n=5) Reilly
PubH 7450, ***Survival Analysis*** (3 cr, fall, n=30) Pan
PubH 7460, ***Advanced Statistical Computing*** (3 cr, fall, n=17) Connett
PubH 7465, ***Biostatistics Consulting Seminar*** (2 cr) *
PubH 7475, ***Statistical Learning and Data Mining*** (3 cr, spring, n=6) Pan)*
PubH 7494, ***Biostatistics Master's Project***
PubH 7496, ***Master's Project Biostatistics***

Biostatistics Ph.D. Courses

PubH 8400, ***Topics in Biostatistics: Seminar in Stat Genomics*** (1 cr, fall, n=4) Reilly
PubH 8400, ***Topics in Biostatistics: Statistical Learning and Data Mining***
(3 cr, spring, n=6) Pan
PubH 8400, ***Topics in Biostatistics: Statistical Genetics II***
(3 cr, spring, n=6) Li/Wu
PubH 8422, ***Modern Non-Parametrics***
(2 cr, fall, n=7) Basu
PubH 8432, ***Probability Models for Biostatistics*** (3 cr, fall, n=5) Banerjee
PubH 8435, ***Latent Variable Models***
(3 cr, fall, n=1) Wall
PubH 8442, ***Biostatistical Decision Theory*** (3 cr, spring, n=10) Reilly
PubH 8445, ***Statistics in Genetics & Molecular Biology*** (3cr, spring, n=3) Reilly
PubH 8452, ***Analysis of Longitudinal Data*** (3 cr)*
PubH 8462, ***Advanced Survival Analysis*** (3 cr)*
PubH 8472, ***Spatial Biostatistics*** (3 cr, fall, n=5) Carlin
PubH 8482, ***Sequential Analysis***
(2 cr)*
PubH 8494, ***Research in Biostatistics***

Enrollment and Total Credit Hours Taught

	SPH Service Courses		Biostatistics Program Courses	
	Enrollment	*Total Credits**	*Enrollment*	*Total Credits**
Fall 2004	295	912	162	508
Spring 2005	214	773	189	567
Summer 2005	55	165	5	5
Fall 2005	393	870	145	445
Spring 2006	242	882	175	543
Summer 2006	77	231	1	1
Fall 2006	328	1062	162	481
Spring 2007	264	940	192	565
Summer 2007	126	326	3	1

** credits hours x enrollment*

Seminars

September 20
Jim Hodges (Division of Biostatistics, University of Minnesota – Twin Cities)
A Spatially-Adaptive Dynamic Conditionally Autoregressive Model for Longitudinal Periodontal Data

September 27
Chap Le (Division of Biostatistics, University of Minnesota – Twin Cities)
A Solution for the Most Basic Optimization Problem Associated with an ROC Curve

October 11
Tim Hanson (Division of Biostatistics, University of Minnesota – Twin Cities)
Some Bayesian Semiparametric Approaches to Modeling Survival/Reliability with a Noisy Longitudinal Marker

October 18
Lan Wang (Department of Statistics, University of Minnesota – Twin Cities)
Consistent Model Selection and Data-driven Smooth Tests for Longitudinal Data in the Estimating Equations Approach

October 25
Moulinath Banerjee (Department of Statistics, University of Michigan)
Interval Censored Data: Some Recent Developments

November 8
Melanie Wall (Division of Biostatistics, University of Minnesota – Twin Cities)
Multiple Indicator and Multivariate Discrete State Hidden Markov Models

November 15
Peter Mueller (Biostatistics, MD Anderson Cancer Center)
FDR, ODP and Bayesian Decision Rules

January 31
Philip Dawid (University College, London)
Interpreting DNA profile evidence in complex disputed paternity cases: Bayesian networks to the rescue

February 14
Daniel P. Normolle, Ph.D. (Associate Professor, Biostatistics, University of Michigan)
The Colorectal Cancer Serum Proteomics Bakeoff

February 21
Holly Janes, Ph.D. (John Hopkins University, Bloomberg School of Public Health)
Partitioning Evidence of Statistical Association: A Case Study of Air Pollution and Mortality

February 28
Jeff Sloan, Ph.D. (Mayo Clinic Rochester)
Clinical Trials and Clinical Significance of Quality of Life Endpoints in Oncology

March 7
Deepak Agarwall (Senior Research Scientist, Yahoo!)
Research Bayesian Spatial Scan Statistic Adjusted for Over Dispersion and Spatial Correlation

March 19
J. Michael Oakes, PhD (Division of Epidemiology & Community Health, Minnesota Population Center, University of Minnesota Twin Cities)
Beyond the RCT: Some Overlooked Challenges to Statistical Inference in Human Health Research

March 28
Erin Conlon (Department of Math/Stat., University of Massachusetts)
Statistical Methods for Integrating Multiple Sources of Genomic Data

April 4
Bhramar Mukherjee (Department of Biostatistics, University of Michigan)
Bayesian Analysis of Studies of Gene-Environment Interaction

April 18
Heping Zhang (Department of Epidemiology and *Public Health, Yale University School of Medicine)*
Genetic Studies for Ordinal Traits

April 25
Tom Louis (Department of Biostatistics, Johns Hopkins University)
Bayesian Analysis of the 1918 Influenza Pandemic in Baltimore, MD and Newark, NJ

May 2
David Nelson, (Center for Chronic Disease Outcomes Research, Minneapolis VA Medical Center)
Bias Reduction versus Sufficient Dimension Reduction

May 16
Jim Hodges (Division of Biostatistics, University of Minnesota – Twin Cities)
Treatment of Periodontal Disease and the Risk of Preterm Birth: The Obstetrics and Periodontal Therapy (OPT) Trial

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Access to Hospice for Rural and Minority Elders

Personnel: Beth A. Virnig (Division of Health Policy/Management), Principal Investigator
Bradley P. Carlin, Co-Investigator
Agency: American Cancer Society
Total Award: $651,000

This project will assess the geographic availability of hospice services, focusing on rural and minority populations, and examine access to symptom management care for cancer patients in a hospice context.

Antifibrotic Drug Discovery in Acute Lung Injury

Personnel: Peter B. Bitterman (Medicine), Principal Investigator
Cavan S. Reilly, Co-Investigator
Agency: National Institutes of Health
Total Award: $1,871,140

The investigators propose that pathological persistence of fibroblasts in the healing lung may result from aberrant translational activation of mRNAs encoding critical antiapoptotic proteins - and hypothesize that therapies capable of titrating cap-dependent translation to physiological levels have the potential to restore sensitivity of lung fibroblasts in the healing lung to apoptosis.

Bcl-2 selective inhibitors: development and application to cancer treatment

Personnel: Chengguo Xing (Pharmacy), Principal Investigator
Timothy Hanson, Co-Investigator
Agency: National Institutes of Health
Total Award: $836,809

The specific aims are to:
Identify a set of inhibitors for Bcl-2, Bcl-XL, and Bcl-w with stringent selectivity (two for each protein). We will 1) rationally design and synthesize a 72-member library based on a promising template by using molecular modeling and solid-phase synthesis; 2) identify the selective inhibitors by a solid-phase assay; and 3) determine their absolute binding selectivity. 2. Examine the effect of binding selectivity on the potential for selective toxicity to tumors over healthy tissues and the potential of sensitizing tumors to conventional cancer treatment.

The project will 1) evalute our current selective and non-selective inhibitors for their cytotoxicity against hematologic primary tumors and healthy blood cells; 2) evaluate our current selective inhibitors for their potential synergism with clinical therapies against the hematologic primary tumors.

Benzo{a}pyrene Metabolism: Phenotyping and Genotyping

Personnel: Stephen S. Hecht (Cancer Center), Principal Investigator
Chap T. Le, Co-Investigator
Agency: National Institutes of Health
Total Award: $1,856,250

In this project, we propose to integrate genotyping data with PAH metabolite profiles and DNA adduct levels in humans. The goal is to develop a practical method for assessing individual differences in human PAH metabolic activation and detoxification.

Biology and Transplantation of the Human Stem Cell - Core B

Personnel: Philip B. McGlave (Medicine), Principal Investigator
Chap T. Le, Director of Biostatistics Core
Tracy Bergemann, Co-Investigator
Agency: National Institutes of Health
Total Award: $7,336,597

The proposed program project grant is a focused, integrated effort to characterize the hematopoietic stem cell and to develop methods for ex vivo selection and expansion of stem cells suitable for human clinical transplantation therapy. This project will greatly expand our understanding of human hematopoietic stem cell biology and will accelerate the transition from basic stem cell biology studies to the application of stem cell transplantation therapy for a variety of malignant diseases.

Blood and Marrow Transplant Program Project, Biostatistics Support Group

Personnel: **Chap T. Le,** Co-director of Office of Clinical Trials
Total Budget: $777,000

The Biostatistics Support Group provides biostatistical help for research in blood and bone marrow transplantation and has designed and maintains the BMT database for all patients who have received transplants at the University of Minnesota. The Biostatistics Support Group is supported by a variety of sources including the University of Minnesota Comprehensive Cancer Center Grant, the Stem Cell Program Project, Fairview University Medical Center, and several pharmaceutical company contracts.

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Carcinogenic Cyclic Nitrosamine DNA Adducts

Personnel: Stephen S. Hecht (Cancer Center), Principal Investigator
Chap T. Le, Co-Investigator
Agency: National Institutes of Health
Total Award: $1,648,240

The goal of this study is to determine the structures of DNA adducts formed by cyclic nitrosamines and related aldehydes in vitro and in vivo.

Center for Health Trajectory Research

Personnel: Jean Wyman (Nursing), Principal Investigator
Cynthia Davey, Research Fellow
Agency: National Institute of Nursing Research
Total Grant: $1,500,000

Funded by a five-year grant of $1.5 million from the National Institute of Nursing Research, the Center for Health Trajectory Research (1P20-NR008992) supports interventions that promote, maintain and restore health from infancy to old age. This new exploratory research center builds research infrastructure in the School of Nursing, as well as knowledge development in the science of intervention research. The goal is to influence the trajectory or pathway that individuals and/or families experience with developmental, transitional, acute, or chronic health challenges in order to influence optimal health outcomes across the lifespan. Each year the Center supports pilot projects related to the theme.

University of Minnesota Comprehensive Cancer Center

Personnel: John H. Kersey, Director (Until March 2007)
Dough Yee, Director (Starting March 2007)
Chap T. Le, Director of the Biostatistics Core Collaborative with Medical School, University of Minnesota
Agency: National Institutes of Health (NCI)
Total Grant: $17,611,807

The mission of the University's Comprehensive Cancer Center is to create a collaborative environment that advances knowledge about the causes, prevention, detection, and treatment of cancer and to apply that knowledge to patient treatment. The Comprehensive Cancer Center consists of 8 research programs and several core units. The Biostatistics Core supports all aspects of cancer studies, from study design, randomization, registration, data collection, processing, quality control, data storage and retrieval to data analysis. Major activities are in statistical consulting and protocol reviews.

A Clinic-Based Intervention Targeting Primary and Secondary Prevention of childhood Obesity

Personnel: Martha Y. Kubik (Nursing), Principal Investigator
Cynthia Davey, Research Fellow
Agency: Allina Hospitals and Clinics
Total Award: $45,454

The pilot study will develop, implement, and evaluate a clinic-based BMI measurement and behavioral counseling intervention to increase health provider assessment of annual BMI in children and delivery of targeted behavioral counseling to parents and children. This project ended May 2007.

Clinical Coordinating Center for Feasibility Study of Retinoid Therapy for Emphysema

Personnel: **John E. Connett,** Principal Investigator
Agency: National Institutes of Health (NHLBI)
Total Grant: $1,390,285

The purpose of this project is to establish and operate a clinical coordinating center for feasibility studies of retinoic acid as a possible treatment for emphysema. The clinical coordinating center participates in design, data processing and management, statistical analysis of data, and authorship of recommendations, evaluations and publications.

COPD Clinical Research Network - Data Coordinating Center

Personnel: **John E. Connett,** Principal Investigator
Christine H. Wendt (Medicine), Co-Investigator
Agency: National Institutes of Health
Total Award: $5,168,621

The Division of Biostatistics in the School of Public Health at the University of Minnesota, in collaboration with the Divisions of Epidemiology and Pulmonary Medicine, operates the Data Coordinating Center (DCC) for the Chronic Obstructive Pulmonary Disease Clinical Research Network. The goals of the Network are to identify preventive and therapeutic interventions to reduce mortality, exacerbations, and disability in

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patients with moderate-to-severe COPD. Clinical trials undertaken by the Network must have relevance to clinical practice for the treatment of this common and serious chronic disease, and must provide efficient answers to questions regarding treatment alternatives.

COPD - The Effect of Macrolide Administration on the Frequency and Severity of COPD Exacerbations

Personnel: **John E. Connett,** Principal Investigator
Agency: National Institutes of Health
Total Award: $4,347,215

These funds will allow for the purchase, packaging, and handling of study agents for the macrolide protocol.

Damage to the Lymphoid Niche and Timing of HIV Therapy

Personnel: Timothy W. Schacker (Medicine), Principal Investigator
Cavan S. Reilly, Co-Investigator
Agency: National Institutes of Health
Total Award: $1,306,596

The specific aims proposed in this project are to determine 1) if measurement of collagen and other products of inflammation in lymphatic tissue will provide information about potential for immune reconstitution and 2) if collagen is reduced and the niche is restored with HAART. Successful completion of these proposed studies may provide new insight into the pathogenesis of CD4+ T cell depletion and the kinetics of immune reconstruction as well as a more relevant measure of potential for response to therapy than those currently in use.

Do Family Meals Matter?

Personnel: Dianne Neumark Sztainer (Epidemiology), Principal Investigator
Melanie M. Wall, Co-Investigator
Agency: General Mills Bell Institute of Health and Nutrition
Total Award: $124,998

A five-year longitudinal analysis of associations between family meals and behavioral, psychosocial, and physical outcomes in adolescents.

Early Detection of Gastrointestinal Nerve Degeneration

Personnel: Gwen Crabb (Neurology), Principal Investigator
James S. Hodges, Co-Investigator
Agency: Juvenile Diabetes Foundation
Total Award: $148,528

We propose to study mucosal nerves of the stomach in type I candidates for pancreas transplantation to further characterize our initial findings, to develop specific criteria for diagnosis of neuropathy, and to quantify enterocyte hypertrophy. We will also determine whether epidermal nerves can act as surrogates for diagnosis of enteric nerve pathology. In addition to diagnosis, the results will provide new information about the innervation of the normal and diabetic stomach, lead to better understanding of the neural basis of abnormal accommodation, delayed gastric emptying and fluctuating hypo- and hyperglycemia, and stimulate research in this field. This research should lead to better patient understanding of the factors that complicate blood glucose control thereby leading to improved management. We hope the research will stimulate development of instruments to promote scheduled gastric emptying as a means to prevent hypoglycemia. It can also provide surgeons with knowledge of the motility potential of operated diabetic intestine for more rational therapy of postoperative intestinal stasis.

Effectiveness of a Machine Guarding Intervention

Personnel: **Wei Pan,** Principal Investigator
Agency: National Institutes of Health (Subcontract to Park Nicollet)
Total Grant: $40,101

The purpose of this study is to assess the effectiveness of interventions designed to lower the risk of amputation and related injuries by increasing the availability and use of machine guards in small manufacturing shops (4-50 employees). The effectiveness of interventions will be evaluated at two levels: 1) minimal (control) and 2) intervention directed at both owners and employees. Individual machine guarding assessments will be used to measure availability and adequacy of guards and to develop prioritized recommendations. Shops will be recruited from the St Paul/Minneapolis metropolitan area. In intervention shops, peer trainers will deliver education and technical assistance to owners and employees.

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Effect of Maternal Periodontitis on Infant Neurodevelopment

Personnel: Bryan S. Michalowicz (Dentistry), Principal Investigator
James S. Hodges, Co-Investigator
Agency: National Institutes of Health
Total Award: $3,243,294

This study's purpose is to determine if treating periodontitis before 20 weeks gestation is associated with changes in measures of infant mental, motor, and language development.

Epidemiology of Infant Leukemia

Personnel: Julie A. Ross (Cancer Center), Principal Investigator
Chap T. Le, Co-Investigator
Agency: National Institutes of Health
Total Award: $1,305,180

This case-control study will investigate the environmental exposures in utero that may be important to the development of leukemia in infancy. Dr. Le's role began 4/1/04.

Epilepsy Clinical Research Program

Personnel: Ilo E. Leppik (College of Pharmacy), Principal Investigator
Judith M. Garrard (Health Services Research and Policy), Principal Investigator
Lynn E. Eberly, Co-Investigator
Agency: National Institutes of Health
Total Grant: $6,406,739

The elderly are the fastest growing demographic group in the U.S., and recent research has shown that use of drugs for epilepsy is very common in this age group (10% of 45,000 nursing home residents). We will study antiepileptic drug metabolism using liver biopsy tissue from elderly with stable (non-radioactive) and labeled tracer drugs. A sophisticated computer system will be used to investigate patterns of antiepileptic drug metabolism and use from over 6,000 nursing home patients in the U.S. Also, we will be studying the risk factors for developing epilepsy in 16,000 African-Americans and Caucasians.

Expert Decision-making in Exposure Assessment

Personnel: Gurumurthy Ramachandran (Environmental and Occupational Health), Principal Investigator
Sudipto Banerjee, Co-Investigator
Agency: National Institutes of Health
Total Award: $556,875

The goals of this research project are: 1) to assess the accuracy of subjective assessments of exposure by occupational hygienists (such as seniority, exposure, exposure assessment experience, educational backgrounds), 2) to determine the sensitivity of subjective exposure assessments to these determinants; and 3) to develop a Bayesian probabilistic framework for efficient decision-making regarding exposures that integrates actual monitoring data and subjective estimates of exposure to arrive at correct decisions using the least number of measurements.

The Family Blood Pressure Program - HyperGEN

Personnel: James S. Pankow, (Epidemiology), Principal Investigator
Na (Michael) Li, Co-Investigator
Agency: National Institutes of Health/NHLBI
Total Award: $225,935

A network of collaborating institutions that study hypertensives and their siblings to identify how heredity and environment interact in producing high blood pressure. (HyperGEN)

Functional Genomic Analysis of HIV-1 Infection in LTs

Personnel: Ashley T. Haase (Microbiology), Principal Investigator
Cavan S. Reilly, Co-Investigator
Agency: National Institutes of Health
Total Award: $2,572,326

Lymphatic tissues are the major site of HIV-1 replication, persistence and pathology prior to anti-retroviral treatment. After treatment suppresses viral replication, the pathological changes can be reversed to a variable extent. With the objective of identifying molecular bases for the pathological and reparative processes in HIV-1 infected lymphatic tissues, a preliminary microarray study was undertaken of gene expression in lymph node biopsies from HIV-1 infected patients before and after treatment. The study revealed a set of

Grants and Funding

treatment-responsive genes related to host defenses, inflammatory pathology, and tissue repair. The overall objective of the proposed studies is to extend the gene profiling studies to gain further insight into the pathogenesis of HIV-1 infection in lymphatic tissues and the response to treatment that will translate into optimal timing and effectiveness of treatment. To this end, in specific aim 1 larger numbers of patients at different stages of HIV-1 infection will undergo lymph node biopsies for microarray analysis prior to and after antiretroviral treatment. In specific aim 2, in situ hybridization, immunohistochemical staining and quantitative image analysis will be used to link changes in gene expression to cells and anatomic sites and structures. Collectively, insights into pathological and reparative processes could lead to new approaches to decreasing the pathological consequences of infection and to new therapeutic strategies to enhance immune reconstitution.

Gene Polymorphism and Kidney Transplant Outcome

Personnel: Elizabeth Seaquist (Medicine), Principal Investigator
John E. Connett, Co-Investigator (through June 30, 2006)
Wei Pan, Co-Investigator (through December 31, 2006)
Agency: National Institutes of Health
Total Grant: $1,037,075

The major goal of this proposal is to determine if common polymorphic alleles in biologically relevant genes, in either the recipient or the donor genome, influence kidney transplant outcome.

General Clinical Research Center

Personnel: David M. Brown (Pediatrics), Director
William Thomas, Director of Statistics and Computing
Na (Michael) Li, Biostatistician
Agency: National Institutes of Health
Total Grant: $16,004,985

The General Clinical Research Center (GCRC) offers opportunities for health science faculty, fellows and students to conduct clinical studies in a setting specifically designed for research. Nursing, dietary, statistics, and computer science personnel are available to provide support and consultation to investigators, from study design and meal planning through data collection and analysis.

Genetic Epidemiology of Osteosarcoma

Personnel: Logan G. Spector (Pediatrics), Principal Investigator
Tracy Bergemann, Co-Investigator
Agency: National Institutes of Health
Total Award: $1,680,894

Using the resources of the Children's Oncology Group (COG), we propose to conduct the largest and most comprehensive genetic investigation of pediatric Osteosarcoma to date. This study will employ the case-parent triad design to study main effects of genes related to bone growth and DNA integrity. Gene x environment and gene x gene interaction will also be explored. Over a three year period about 470 children diagnosed with OS at North America COG institutions will be enrolled along with their parents. Buccal cells will be collected through the mail for genotyping. Exposure data will also be collected through mailed surveys of parents and children. In this study we will examine 33 variants in twelve candidate genes.

Genetic Heterogeneity in Endothelial Gene Expression

Personnel: Robert P. Hebbel (Medicine), Principal Investigator
Wei Pan, Co-Investigator
Agency: National Institutes of Health
Total Award: $1,503,845

This project examines BOEC for gene expression in context of being at-risk for stroke in sickle disease.

Genomics of Kidney Transplantation

Personnel: Arthur J. Matas (Surgery), Principal Investigator
John E. Connett, Saonli Basu, Na (Michael) Li, Co-Investigators
Agency: National Institutes of Health
Total Award: $8,833,736

The project proposes to study whether genetic variants are, in part, responsible for the differing outcomes of transplant recipients treat with similar immunosuppressive protocols.

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Graduate Training in Biostatistics

Personnel: **John E. Connett,** Program Director
Agency: National Institutes of Health
National Research Service Award
Total Grant: $1,367,892

This program is designed to prepare pre- and post-doctoral students for research careers in biostatistics, with emphasis on clinical trials and observational studies in AIDS. Trainees work closely with investigators in the Community Programs for Clinical Research on an AIDS project (CPCRA) and other HIV/AIDS studies, and have the opportunity to do original analytic studies on large, well-documented data sets from completed clinical trials and epidemiological studies.

Health Service Use in the Elderly with Cancer

Personnel: Alexander M. McBean (Health Services Research and Policy), Principal Investigator
Sudipto Banerjee (Co-Investigator)
Agency: National Institutes of Health
Total Award: $821,949

This project will test whether recommended clinical preventive services and quality of care guidelines are met as frequently among elderly Americans who develop cancer as among elderly persons with cancer.

Hierarchical Modeling Approaches for Geographical Boundary Analysis in Cancer

Personnel: **Sudipto Banerjee,** Principal Investigator
Bradley P. Carlin, Co-Investigator
Agency: National Institutes of Health
Total Award: $718,287

Boundary analysis concerns the detection and analysis of zones of abrupt change in spatial maps. Its importance in understanding scientific phenomena has been widely recognized in fields such as genetics and ecology. However, current methods are based upon rather ad-hoc deterministic algorithms. This project is designed to develop formal statistical methods for carrying out boundary analysis, exploiting modern GIS tools to advance the development and interpretation of boundary analysis in spatial (cancer-related) maps. Attendant benefits of the project will include enhancements in the understanding of spatial structure associated with information displayed in cancer-related maps. Goals of this project include development of boundary analysis from an inferential perspective with evaluation of statistical modeling approaches using cancer data from the Minnesota Cancer Surveillance System (MCSS), the Iowa Women's Health Survey (IWHS), the Surveillance Epidemiology and End Results (SEER) (http://seer.cancer.gov) database of the National Cancer Institute as well as Medicare usage and cancer hospice mortality data.

Hierarchical models for Large Geostatistical Datasets with Application

Personnel: **Sudipto Banerjee,** Principal Investigator
Agency: National Science Foundation
Total Award: $253,511

This proposal lays down a comprehensive framework for carrying out statistical inference on point-referenced spatial data that are available from a large number of locations. The focus of the proposal is methodological rather than purely theoretical or purely applied.

Hypergen: Genetics of Left Ventricular Hypertrophy

Personnel: **Na (Michael) Li,** Principal Investigator
Agency: National Institutes of Health (Subcontract to University of Alabama)
Total Award: $111,798

A network of collaborating institutions that study hypertensives and their siblings to identify how heredity and environment interact in producing high blood pressure.

Identifying Factors Influencing the Survival of Kidney Allographs by Genomic and Proteomic Analysis.

Personnel: William S. Oetting (Pharmacy), Principal Investigator
Baolin Wu, Co-Investigator
Agency: State of Minnesota
Total Award: $480,000

The central hypothesis guiding these studies is that AR and CPAD are intimately interrelated entities and that allograft inflammation is at least one of the pathogenic mechanisms linking these two conditions.

Grants and Funding

Identifying Susceptibility Genes for Metabolic Syndrome

Personnel: James S. Pankow (Epidemiology), Principal Investigator
Na (Michael) Li, Co-Investigator
Agency: National Institutes of Health
Total Award: $1,098,578

Our goal is to characterize the genomic region between 2a35-2q37 using linkage disequilibrium (LD) mapping to identify metabolic syndrome (MS) genes. The MS is defined by the National Cholesterol Education Program Adult Treatment Panel III as the joint occurrence of at least three abnormalities: abdominal obesity, high triglycerides, low HDL, hypertension, or fasting hyperglycemia.

Impact of Mind-Body Intervention Post Organ Transplant

Personnel: Cynthia R. Gross (Experimental & Clinical Pharmacology), Principal Investigator
William Thomas, Co-Investigator
Agency: National Institutes of Health
Total Award: $2,108,223

This project's long-range objectives are to develop evidence-based recommendations for non-pharmacological strategies that provide symptomatic relief to transplant recipients, and are safe, practical, and cost-effective.

Infectious Disease Clinical Research Program (IDCRP) – Data Analysis Center

Personnel: Alan R. Lifson (Epidemiology), Principal Investigator
Kathy Huppler Hullsiek, Gregory A Grandits, Co-Investigators
Ann M. Fieberg, Mollie P. Roediger, Research Fellows
Agency: Henry Jackson Foundation
Total Award: $819,463

This project is for a Data Analysis Center (DAC) at the University of Minnesota to support the Infectious Disease Clinical Research Program (IDCRP). The DAC will provide the statistical and epidemiological expertise necessary for the design, implementation, analysis, and publication of IDCRP observational studies and clinical trials.

International Network for Strategic Initiatives in Global HIV Trial (INSIGHT)

Personnel: **James D. Neaton,** Principal Investigator
Agency: National Institutes of Health
Total Award: $12,500,000

The International Network for Strategic Initiatives in Global HIV Trials (INSIGHT) is an HIV clinical trial network. Its research will focus on the optimization of clinical management, including co-morbidities, in persons afflicted with HIV. INSIGHT will conduct large, long-term, randomized trials at approximately 400 sites in 37 countries. INSIGHT components currently conduct the ESPRIT, SMART, and STALWART trials that include nearly 10,000 patients and a large genomics study. Additional trials will be included during the 5-year project period.

Investigation of the Genetics of Asthma

Personnel: Malcolm N. Blumenthal (Medicine), Principal Investigator
John E. Connett, Co-Investigator
Cavan S. Reilly, Co-Investigator
Agency: National Institutes of Health
Total Award: $3,978,587

The overall goals of this project are to determine if asthma is a unique disease or a 'cluster' of distinct disorders and identify the genes responsible for their development. These goals will be pursued in the following specific aims: 1. Establish quantitative traits predisposing to asthma, and apply statistical cluster analyses to these traits among the Minnesota Families. 2. Identify the chromosomal regions responsible for these multicomponent phenotypes, using multipoint linkage analyses. 3. Identify candidate genes in these mapped areas responsible for the components predisposing to asthma by using genetic fine mapping and DNA sequence analysis. This study will utilize the extensive data already collected on families through the CSGA and a novel approach to identify asthma susceptibility genes. This will be the first step in the identification of genes that can be used for predictive genetic analyses and development of drug targets for this common medical problem.

Grants and Funding

Latent Variable Models and Methods for Behavioral Health Data in Public Health

Personnel: **Melanie M. Wall,** Principal Investigator
Agency: National Institutes of Health
Total Award: $563,255

The specific aims of this project are 1. To bridge the gap between categorical and continuous latent variable models with specific attention put on modeling the structural relationship between continuous and categorical latent variables 2. To develop methods for modeling nonlinear relationships between both continuous and categorical latent variables 3. To develop methods for modeling multivariate longitudinal data with both continuous and categorical latent variable models. A final, overarching aim of this proposal is to use the methods and models developed to answer research questions relevant for public health in the specific areas of adolescent health compromising behavior, and medical outcomes for adult alcoholics.

Long-term Deterioration of Kidney Allograft Function

Personnel: Arthur J. Matas (Surgery) Principal Investigator
John E. Connett, Core Principal Investigator
Robert E. Leduc, Senior Statistician
Agency: National Institutes of Health
Total Award: $9,475,697

This project will carry out a multi-center, prospective study to accurately describe the natural history of late kidney transplant failure and to dissect histologic and other factors leading to late deterioration of function and to graft loss.

Reliability of Passive Safety Systems (Sandia LDRD 06-0162

Personnel: **Timothy Hanson,** Principal Investigator
Agency: Sandia National Laboratories
Total Award: $70,235

The goal of this project is to develop joint longitudinal-reliability models for real-time monitoring of next generation nuclear reactor safety systems. The first phase of the project investigates the predictive utility of various discrete and continuous time models for atmospheric corrosion data obtained from automated test chip bond pads exposed to fixed NaCl, humidity, and temperature in a controlled, accelerated experimental setting. This project ended September 15, 2006.

Lung Cancer Chemoprevention: Isothiocyanate, inositol

Personnel: Stephen S. Hecht (Cancer Center), Principal Investigator
Chap T. Le, Co-Investigator
Agency: National Institutes of Health
Total Award: $3,822,534

The goal of this proposal is to carry out translation research to further develop these agents for chemoprevention of lung cancer in smokers and ex-smokers.

Maternal Immunization to Prevent Infant Otitis Media

Personnel: Patricia Ferrieri (Pediatrics), Principal Investigator
Patricia M. Grambsch, Co-Investigator
Agency: National Institutes of Health (NIDCD)
Total Grant: $3,241,588

This Phase 1-2 clinical trial will determine if infants of women immunized with 9-valent PCV (PCV9) and infants of control women who receive placebo during the third trimester of pregnancy have equivalent anti-capsular polysaccharide (PS) IgG antibody responses to PCV7 measured one month after the third vaccine injection at 6 months of age, to compare local and systemic adverse events among women immunized with PCV9 or placebo, and to investigate the hypotheses that (1) maternal immunization does not interfere with the infant's antibody subclass and pneumococcal opsonic responses to the primary PCV7 vaccine series or to booster PCV7 dose at 12 months, (2) pregnant women have a significant antibody response to PCV9 vaccine compared to placebo vaccine and increased antibody persists 13 months after delivery, (3) anti-PS IgG and secretory IgA antibodies are present in the milk of immunized lactating women, and (4) maternal immunization does not interfere with the infants' antibody response to H influenza type b conjugate and diphtheria toxoid vaccines.

Metabolic Syndrome Following Transplant for Leukemia

Personnel: Kevin Baker (Pediatrics), Principal Investigator
Chap T. Le, Co-Investigator
Agency: National Institutes of Health
Total Award: $2,208,973

The goal of this project is to study the prevalence and characteristics of the metabolic syndrome in children who have survived cancer.

Grants and Funding

Metabolic Syndrome in Childhood Cancer Survivors

Personnel: Julia Steinberger (Pediatrics), Principal Investigator
Chap T. Le, Co-Investigator
Agency: National Institutes of Health
Total Award: $2,070,371

The goal of this study is to examine differences in insulin resistance metabolic syndrome risk factors and endo-thelial function in children who survived cancer.

Statistical Methods for Genomic and Proteomic Data

Personnel: **Wei Pan,** Principal Investigator
Agency: National Institutes of Health
Total Grant: $795,124

The goal of this research is to develop, evaluate and compare statistical methods in analyzing and interpreting microarray data.

MRS and MRI of Breast Cancer at Very High Magnetic Fields

Personnel: Michael Garwood (Radiology), Principal Investigator
Lynn Eberly, Biostatistician
Agency: National Institutes of Health
Total Grant: $1,652,065

The general goal of this research is to develop and test improved magnetic resonance spectroscopy (MRS) methods optimized for diagnosing breast lesions noninvasively with very high magnetic field (3 and 4 Tesla) MR systems.

Mindfulness Versus Pharmacotherapy Pilot Study for Insomnia (MVP #1)

Personnel: Cynthia R. Gross (Experimental & Clinical Pharmacology), Principal Investigator
Melanie M. Wall, Co-Investigator
Agency: University of Minnesota Academic Health Center
Total Award: $244,715

The purpose of this pilot project is to obtain key data for establishing feasibility and determining the optimal design for an NIH grant to support a full-scale RCT comparing Mindfulness-Based Stress Reduction training to drug therapy for chronic insomnia.

Minneapolis Heart Institute Foundation

Personnel: **James S. Hodges,** Principal Investigator
Agency: Minneapolis Heart Institute Foundation
Total Award: $31,451

Dr. Hodges will work with the Minneapolis Heart Institute researchers to design, execute, analyze, and report research projects related to heart disease and treatment.

A Multidisciplinary Scholar Development Program to Advance Clinical Research (K12)

Personnel: Russell V. Luepker (Epidemiology)
James D. Neaton, Co-Investigator
William Thomas, Co-Investigator
Agency: National Institutes of Health
Total Award: $2,148,375

This K12 project embraces the spectrum of training of clinical research from observational epidemiology to clinical trials to outcomes research.

National Institute for Nursing Research Informatics based nurse triage in lung transplant care

Personnel: Stanley M. Finkelstein (Lab, Medicine and Pathology), Principal Investigator
Bradley P. Carlin, Co-Investigator
Lynn E. Eberly, Data Safety Monitoring Board
Agency: National Institutes of Health
Total Award: $1,974,117

The project's long-term objective is to improve the health status of lung transplant recipients by providing a means for the early detection of acute bronchopulmonary events, resulting in earlier and timelier intervention and improved outcome.

Grants and Funding

NK Cells, Their Receptors and Unrelated Donor Transplant

Personnel: Jeffrey S. Miller (Medicine), Principal Investigator
Chap T. Le, Core Director
Tracy L. Bergemann, Co-Investigator
Agency: National Institute of Health
Total Award: $14,620,945

This program is designed to understand the role of NK cells in unrelated donor allogeneic transplant. The biostats core is involved in clinical trial design (Project) and laboratory assessment of NK cell receptors and their function (Projects 1 and 2) between donor/recipient pairs undergoing this procedure for hematoligic malignancies. The ultimate goal of this project is to manipulate NK cells to improve transplant outcomes.

Otitis Media Core Center

Personnel: Kathleen A. Daly (Otolaryngology), Principal Investigator
Cynthia Davey, Research Fellow
Agency: National Institutes of Health
Total Grant: $2,058,203

The Otitis Media Core Center will support sixteen currently NIH-funded base research projects and an additional two recently submitted projects. The research is focused on basic molecular, cellular, microbial, immunological, animal modeling, population science, and clinical studies. The Biostatistics Core is responsible for study design, data collection and processing, quality control, data storage and retrieval, and data analysis, to provide investigators with a high level and broad range of expertise in data management and analysis.This project ended November 2006.

Organ Transplantation in Animals and Man

Personnel: Arthur J. Matas (Surgery), Principal Investigator
Thomas E. Nevins (Pediatrics), Co-investigator
William Thomas, Statistician Collaborative with Department of Surgery, University of Minnesota
Agency: National Institutes of Health
Total Grant: $4,865,119

This study, part of a large program project, seeks to relate long-term electronic records of prescription-drug bottle-cap opening, specifically evidence of non-compliance, to adverse outcomes after kidney transplantation. A clinical trial of intervention to improve compliance is underway.

Pathogenesis of HIV-Induced Immunodeficiency

Personnel: Ashley T. Haase (Microbiology), Principal Investigator
Cavan S. Reilly, Co-Investigator
Agency: National Institutes of Health
Total Award: $1,976,872

The overall objective of this project is to characterize viral and cellular populations in the lymphatic tissue niche to better understand HIV pathogenesis and improve treatment based on that knowledge.

Pathogenesis and Therapy of Chronic Lung Rejection

Personnel: Marshall I. Hertz (Medicine), Principal Investigator
Na (Michael) Li, Biostatistician
Agency: National Institutes of Health
Total Award: $6,000,000

The goal of this proposal is to improve understanding of the immunopathogenesis, molecular diagnosis and therapy of chronic rejection after lung transplantation.

Pharmacogenetics of Drug Transporters and Triglyceride Response to Fenofibrate

Personnel: Robert J. Straka (Pharmacy), Principal Investigator
Na (Michael) Li, Co-Investigator
Agency: American College of Clinical Pharmacy
Total Award: $29,974

The overall objective of this project is to investigate the impact of three specific genetic variants of a key drug transporter protein and quantify their impact on triglyceride response in patients receiving fenofibrate. The results of the study will advance the ability of clinicians to improve drug selection from the perspectives of both efficacy toxicity.

Grants and Funding

A Phase III Multicenter Randomized Study of the Biological and Clinical Efficacy of Subcutaneous Recombinant, Human Interleukin-2 in HIV-Infected Patients with Low CD4+ Counts Under Active Antiretroviral Therapy (SILCAAT)

Personnel: **James D. Neaton,** Principal Investigator
Agency: Chiron Corporation
Total Grant: $18,000,000

SILCAAT is an international randomized trial to determine whether subcutaneous interleukin-2 (~IL-2 Proleuken) delays progression of AIDS and extends survival among HIV-infected patients with CD4+ cell count ‹ 300 cells/mm3. The study involves 139 clinical sites in 11 countries. A total of 1971 patients have been enrolled and these patients will be followed for at least 4 years.

Predictors of Adult Leukemia

Personnel: Julie A. Ross (Pediatrics), Principal investigator
Chap T. Le (Co-Investigator)
Agency: National Institutes of Health
Total Award: $2,614,947

This case-control study will investigate risk factors for myeloid leukemia in Minnesota adults and will focus on NSAIDs, farming, and genetic susceptibility.

Preventive Health Care in Elderly Cancer Survivors

Personnel: Alexander M. McBean (Health Services Research and Policy), Principal Investigator
Sudipto Banerjee (Co-Investigator)
Agency: National Institutes of Health
Total Award: $414,315

This study will test if recommended clinical preventive services, including cancer screening, as well as diabetes quality of care guidelines, are met as frequently among elderly Americans who have survived breast, uterine, colon and rectal, bladder, or prostate cancer as among elderly persons without cancer.

Project EAT II: A Longitudinal Study

Personnel: Dianne Neumark-Sztainer (Epidemiology), Principal Investigator
Melanie M. Wall, Co-Investigator
Agency: Maternal and Child Health Bureau
Total Award: $1,376,689

This project examines adolescent eating patterns and weight status in a longitudinal study. Adolescents who participated in the first phase of Project EAT will be surveyed to examine changes in their eating patterns and weight status as they progress from early adolescence (ages 11-14) to middle adolescence (15-17), and from middle to late adolescence/young adulthood (ages 18-21). This project ended August 31, 2006.

Preventing Tobacco Abuse in American Indian Nations

Personnel: Jean L. Forster (Epidemiology), Principal Investigator
John S. Poupart (American Indian Policy Center), Principal Investigator
Kris Rhodes (Epidemiology), Program Coordinator
Cynthia Davey, Research Fellow
Agency: Minnesota Partnership for Action Against Tobacco
Total Grant: $488,747

The purpose of this project is to develop an intervention strategy specific to the Twin Cities urban Indian population, that takes advantage of the traditional strength of Indian people, fits Indian cultural practices and beliefs, and identifies the larger social, historical, and policy context within which urban Indian people develop high rates of tobacco misuse. This project ended May 2007.

Research Diagnostic Criteria: Reliability and Validity

Personnel: Eric Schiffman (TMJ and Orofacial Pain), Principal Investigator
Wei Pan, Co-Investigator
Agency: National Institutes of Health
Total Grant: $3,933,302

The aim of this study is to determine the reliability and validity of the Research Diagnostic Criteria for Temporomandibular Disorders (RDC for TMD). The RDC for TMD includes Axis I biomedical diagnoses of TMD and Axis II biobehavioral assessment procedures. In addition, this study will assess several biological markers for their role as potential mediators underlying the biomedical diagnoses.

Grants and Funding

S. Sanguis Adhesion: Molecular Basis of Specificity

Personnel: Mark C. Herzberg (Oral Sciences), Principal Investigator
Saonli Basu, Co-Investigator
Agency: National Institutes of Health
Total Award: $2,523,061

In S. sanguis and S. gordonii, the AMS is hypothesized to be a module of genes and proteins that function as a network to enable adhesion and early biofilm formation. The AMS would then control the specificity of adhesion and early biofilm formation, explaining differences in S. gordonii and S. sanguis as pioneer colonizers.

Self-managed walking improves function in patients with diabetes mellitus and peripheral arterial disease

Personnel: Tracie C. Collins (Medicine), Principal Investigator
James S. Hodges, Co-Investigator
Agency: American Diabetes Association
Total Award: $504,756

The major goal of this randomized trial is to determine the role of a patient-directed exercise program to improve daily function in patients with diabetes mellitus and peripheral arterial disease.

SMART Neurology

Personnel: **James D. Neaton,** Principal Investigator
Agency: National Institutes of Health, Subcontract to Social and Scientific Systems Inc
Total Award: $96,346

The Neurology Substudy will compare 1) changes in neurocognitive functioning, 2) development of symptomatic peripheral neuropathy, and 3) changes in peripheral neuropathy symptoms between the Drug Conservation (DC) and the Viral Suppression (VS) strategies of the SMART Study (CPCRA 065), a multicenter, randomized trial. This project ended September 2006.

Soy Isoflavone Distribution in Biological Fluids as Markers of Prostate Exposure

Personnel: Mindy S. Kurzer (Food Science and Nutrition), Principal Investigator
William Thomas, Co-Investigator
Agency: USDA
Total Award: $149,500

Major goal is to evaluate the distribution of soy isoflavones in bodily fluids in young men after consumption of a defined dose.

Statistical Methods in Cancer Control and Epidemiology

Personnel: **Bradley P. Carlin,** Principal Investigator
Sudipto Banerjee, Cavan Reilly (through July 31, 2006),
Melanie Wall, Co-investigators
Agency: National Institutes of Health (NCI)
Total Grant: $1,244,941

This project will develop and evaluate statistical methods that, when coupled with geographic information systems software, will enable a much more accurate and complete analysis of cancer-related mortality, incidence, screening, staging, and exposure data. Special emphasis will be on developing methods that accommodate the multivariate, longitudinal, and often spatially misaligned nature of data relevant for cancer control efforts. Publicly available state and federal datasets will be used to illustrate the new methods.

Transdisciplinary Tobacco Use Research Center

Personnel: Dorothy J. Hatsukami (Psychiatry), Director
Chap T. Le, Director of the Design and Analysis Core
Agency: National Cancer Institute
Total Grant: $9,227,445

The Transdisciplinary Tobacco Use Research Center (TTURC) has four research projects varying from animal studies to human clinical trials. The targeted populations to be studied vary across the life span including mothers who smoke and medically compromised smokers. The aim is to examine tobacco exposure reduction methods to treat smokers who have been resistant to conventional methods of intervention; reduction serves as a transitional goal toward cessation. The center grant also involves four research projects and three cores: Administration, Biomarkers, and Design and Analysis (Biostatistics).

Tri-Service AIDS Clinical Consortium Data Analysis Center

Personnel: Alan R. Lifson (Epidemiology), Principal Investigator
Kathy Huppler Hullsiek, Gregory A Grandits, Co-Investigators
Ann M. Fieberg, Mollie P. Roediger, Research Fellows
Agency: Henry Jackson Foundation
Total Award: $327,603

This project is for a Data Analysis Center (DAC) at the University of Minnesota to support the Tri-Service AIDS Clinical Consortium (TACC). The DAC will provide the statistical and epidemiological expertise necessary for the design, implementation, analysis, and publication of TACC observational studies and clinical trials in the field of HIV research.

Veteran's Administration Hospital, Minneapolis

Personnel: **James S. Hodges,** Principal Investigator
Agency: Veterans Administration
Total Award: $26,397

Dr. Hodges will initiate, identify, develop, conduct and report on innovative health services research studies in collaboration with CCDOR scientists and practitioners.

James R. Boen Biostatistics Consulting Laboratory

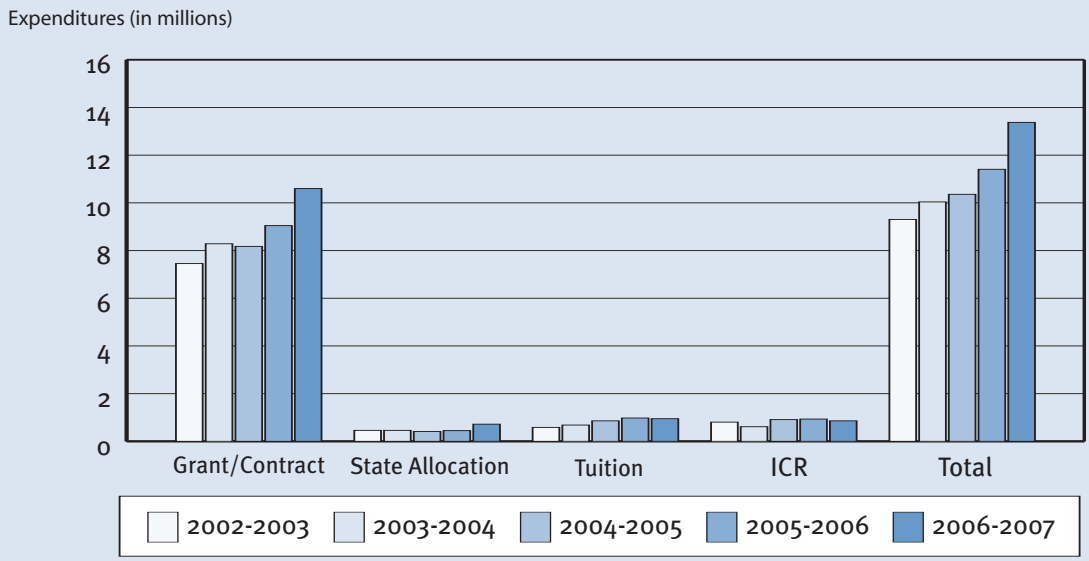
Personnel: **Cynthia Davey,** Research Fellow
Total for year: $129,187

The Division's Biostatistics Consulting Laboratory (BCL) provides statistical consulting and analysis for many projects both within the University and at external facilities, and is a valuable biostatistical resource for researchers in the Academic Health Center. The BCL staff have provided statistical support for several grant proposals. A sample of past and present projects in which the BCL has been involved includes:

- A study of home monitoring of lung function following lung transplantation
- Otitis media clinical and basic science research
- A feasibility study for the collection, storage and transplantation of umbilical cord blood
- A randomized clinical trial of a new CPR technique following cardiac arrest
- A study of failed extubation rates and risk factors in Pediatric intensive care units
- A study of end stage renal disease patient data for quality improvement projects

Funding Profile

Funding for the past 5 years



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Jacqueline Neuhaus, Research Fellow

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Variable selection in penalized model-based clustering via regularization on grouped parameters

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