

NIH Summer Training Institute on the Design and Conduct of Randomized Clinical Trials
Involving Behavioral Interventions

July 29-August 10, 2001

Faculty

Ronald P. Abeles
Special Assistant to the Director
OBSSR/OD/NIH
Gateway Bldg. 2C234 MSC 9205
7201 Wisconsin Avenue
Bethesda, MD 20892-9205

Phone: (301) 496-7859

Fax: (301) 435-8779

E-mail: abeles@nih.gov

Dr. Abeles is a Special Assistant to the Director of the Office of Behavioral and Social Sciences Research in the Office of the Director at the National Institutes of Health. From 1994 to September 1998, he served as the Associate Director for Behavioral and Social Research at the National Institute on Aging (BSR/NIA). Previously he served at BSR/NIA as the Deputy Associate Director (1980-1991) and Acting Associate Director (1991 to 1994). In 1993 he received the National Institutes of Health Award of Merit for "leadership and contributions to the advancement of behavioral and social research on aging." His 1971 doctoral degree in Social Psychology (with a minor in sociology) is from the Department of Social Relations, Harvard University. His experience as a Staff Associate at the Social Science Research Council (1974-78) for the Committee on Work and Personality in the Middle Years and the Committee on Life Course Development stimulated his interest in life course issues. He has organized several symposia at the annual meetings of professional societies, published chapters, and edited books on various aspects of life-course and aging research, most frequently in regard to the sense of control and to the interface between social structure and behavior. He is the editor of *Life-span Perspectives and Social Psychology* (Erlbaum & Associates, 1987), co-editor of *Aging, Health, and Behavior* (Sage Publications, 1993) and of *Aging and Quality of Life* (Springer Publishing Company, 1994), and is an associate editor of the *Handbook of the Psychology of Aging*, Fourth and Fifth Editions (Van Nostrand Reinhold, 1996 and 2001).

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Baruch Brody
Leon Jaworski Professor of Biomedical Ethics
Center for Medical Ethics and Health Policy
Baylor College of Medicine
Houston TX 77030

Phone: 713-798-3503

Fax: 713-798-5678

E-mail: bbrody@bcm.tmc.edu

Baruch A. Brody, Ph.D. is the Leon Jaworski Professor of Biomedical Ethics and Director of the Center for Medical Ethics and Health Policy at Baylor College of Medicine. He is also a Professor of Philosophy at Rice University and Director of the Ethics program at the Methodist Hospital.

Dr. Brody received his B.A. from Brooklyn College in 1962 and his Ph.D. from Princeton University in 1967. He studied at Oxford University as a Fulbright Fellow in 1965-66. He taught at M.I.T. from 1967 to 1975, and has been at Rice since 1975 and at Baylor College of Medicine since 1982.

Dr. Brody is the author and editor of 24 volumes and 120 articles and chapters. His major scholarly works are *Abortion and the Sanctity of Human Life* (M.I.T.: 1975), *Identity and Essence* (Princeton U. Press: 1981), *Life and Death Decision Making* (Oxford: 1988), *Ethical Issues in Drug Testing, Approval and Pricing* (Oxford: 1994), and *The Ethics of Biomedical Research: An International Perspective* (Oxford: 1998). He is currently working on a new book on intellectual property in biotechnology.

Dr. Brody has received four grants from the Office of Technology Assessment of the U.S. Congress to do studies on the ethics of the new reproductive technology, on the ethics of the patenting of transgenic animals, on the ethics of genetic testing in the workplace, and on the ethics of patenting human gene fragments. He has served on five data safety and monitoring boards for the National Heart, Lung, and Blood Institute and currently serves on the DSMB for the AIDS Clinical Trials Group, for the National Eye Institute's Retinitis Pigmentosa Trial and for the NHLBI's ENRICH Trial. He has headed the NASA Bioethics Policy Task Force. He is the principal investigator of the "Protecting Scientific Integrity Through Disclosure of Conflicts of Interest" study (funded by NASA) and of the "Ethical Issues in Emergency Research" study (funded by the NIH). He is a co-investigator in two additional studies, "Enhancing the Autonomy of Vulnerable Subjects of Research" (funded by the NIH) and "Patient Preferences in End-Stage Prostrate Cancer" (funded by the VA). He has helped 11 healthcare institutions organize their ethics committees. He serves on the editorial board and board of directors of the *Journal of Medicine and Philosophy* and on the editorial board of *Social Philosophy and Policy*. Finally, he has served on the national board of the American Philosophical Association, is a Fellow of the Hastings Center, and is a past president of the Society for Health and Human Values.

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Faculty

Leonard H. Epstein

Professor

Departments of Pediatrics, Social and Preventive Medicine and Psychology

University at Buffalo School of Medicine and Biomedical Sciences

G56 Farber Hall

3435 Main Street, Building #26

Buffalo, NY 14214-3000

Phone: 716-829-3400

Fax: 716-829-3993

E-mail: lhenet@acsu.buffalo.edu

Dr. Epstein does basic and applied research on health behaviors, with his primary emphasis on obesity, physical activity and smoking. He and his colleagues are currently studying the effects of Zyban (bupropion) versus placebo on smokers who differ in their dopamine transport genotype (N = 700), and have recently completed clinical trials on prevention of obesity and different ways to decrease sedentary behavior in obese youth. They are planning a new clinical trial on developing alternatives to food reinforcers in obese youth.

Dr. Epstein has served on and chaired the Behavioral Medicine Study Section at NIH, and currently serve on the CSR Advisory Council. He has also been president of the Division of Health Psychology, American Psychological Association.

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Faculty

Alfred Hallstrom
Professor of Biostatistics
University of Washington
1107 NE 45th, Room 505
Seattle, WA 98105

Phone: 206-685-1302

Fax: 206-543-0131

E-mail: aph@u.washington.edu

Al Hallstrom, Ph.D., is a Professor in the Department of Biostatistics at the University of Washington. Since 1974 he has been involved with studies dealing with sudden death, working extensively with data from Seattle and King County Emergency Services programs. These studies have involved several prospective randomized drug trials (propranolol, hydralazine, bretylium, lidocaine); studies of dysrhythmia exhibited on exercise ECG and 24 hour ambulatory ECG in relation to recurrent fibrillation and ventricular function; retrospective studies on antiarrhythmic drugs (quinidine, procainamide, etc.) in survivors of ventricular fibrillation; studies comparing post-myocardial infarction patients with post-cardiac arrest patients; studies of risk factors for recurrent CA; studies of the relationships of smoking to arrest and rearrest. He has also been involved in community based studies of the effect of emergency medical services on survival following out-of-hospital CA and myocardial infarction and in randomized trials of innovative treatments (defibrillation by emergency medical technicians, automatic external defibrillators versus manual defibrillators, alternative CPR techniques, paramedic versus ER administered thrombolysis) in emergency medical services. He has directed the data management and analysis aspects of the Seattle Medic One Survivor Clinic since 1974 and has been a consultant with the King County EMS research group since 1978. From 1979 to 1982 he directed the University Washington Public Health computer facility. Since 1982 he has been, first the Deputy Director, then the Director of the Cardiac Arrhythmia Pilot Study Coordinating Center, the Director of the Cardiac Arrhythmia Suppression Trial Coordinating Center, a Co-Investigator on the Myocardial Infarction and Triage Intervention Trial and a Co-investigator in Dr. Greene's study of the random allocation of CA survivors to conventional therapy versus empiric amiodarone. Currently he directs the ongoing analysis of the AVID study, and two large ongoing multicenter clinical trials; the Public Access Defibrillation (PAD) trial and the Dual Chamber and VVI Implantable Defibrillator (DAVID) trial. He has and continues to serve on numerous DSMB's for multi-center trials in cardiology. In these capacities he gained experience directly applicable to directing Coordinating Center activities for multicenter cardiac (especially emergency medical service and arrhythmia treatment) trials and continues to have a major interest in the resolution of problems concerning the management of arrhythmia. He is interested in clinical trial methodology and management. He is also interested in bluegrass music, junk metal sculpture, and low budget travel.

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Faculty

Robert M. Kaplan
Professor and Chair
Department of Family and Preventive Medicine
University of California, San Diego
9500 Gilman Drive Mail Code 0628
La Jolla, CA 92093-0628

Phone: 858-534-6058

Fax: 858-534-7517

E-mail: rkaplan@ucsd.edu

Dr. Kaplan is Professor and Chair of the Department of Family and Preventive Medicine, at the University of California, San Diego. He is a past President of several organizations, including the American Psychological Association Division of Health Psychology, Section J of the American Association for the Advancement of Science (Pacific), the International Society for Quality of Life Research, and the Society for Behavioral Medicine. He is currently Chair-Elect of the Behavioral Science Council of the American Thoracic Society. Dr. Kaplan is the Editor-in-Chief of the Annals of Behavioral Medicine and Consulting Editor of four other academic journals. Selected additional honors include APA Division of Health Psychology Annual Award for Outstanding Scientific Contribution in 1987, Distinguished Research Lecturer, 1988, and Health Net Distinguished Lecturer in 1991, University of California 125 Anniversary Award for Most Distinguished Alumnus, University of California, Riverside, American Psychological Association Distinguished Lecturer, and the Distinguished Scientific contribution award from the American Association of Medical School Psychologists. His public service contributions include various NIH, AHRQ and VA grant review groups, and service on the local American Lung Association (ALA) Board of Directors and the regional research committee for the American Heart Association. He has served as co-chair of the Behavioral Committee for the NIH Women's Health Initiative, and a member of both the NHLBI Behavioral Medicine Task Force and the Institute of Medicine (IOM) National Academy of Sciences Committee on Health and Behavior. In addition, he is the chair of the Cost/Effectiveness Committee for the NHLBI National Emphysema Treatment Trial (NETT). Dr. Kaplan is the author or co-author of more than a dozen books more than 330 articles or chapters.

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Faculty

Peter G. Kaufmann

Group Leader

NHLBI

II Rockledge Center, Rm. 8118
6701 Rockledge Drive MSC 7936
Bethesda, MD 20892-7936

Phone: (301) 435-0408

Fax: (301) 480-1773

E-mail: Kaufmanp@nhlbi.nih.gov

Dr. Kaufmann is Leader of the Behavioral Medicine Research Group at the National Heart, Lung, and Blood Institute (NHLBI), NIH. He received his doctorate in Psychology in the Biopsychology program at the University of Chicago, and did post-doctoral research in Neurosciences at Duke University, where he investigated cellular excitability of the central nervous system under conditions of environmental stress. After coming to the NHLBI, he applied his knowledge of the neurosciences and psychology to develop studies of the role of stress in coronary heart disease and hypertension. Data from one of these studies, the Psychophysiological Investigation of Myocardial Ischemia (PIMI) provided evidence for mental stress as an independent risk factor for mortality of patients with confirmed coronary artery disease. He was also instrumental in the conduct of several multi-center randomized clinical trials involving behavioral interventions, including the Hypertension Intervention Pooling Project (HIPP), Trials of Hypertension Prevention (TOHP), the Raynaud's Treatment Study (RTS), and Enhancing Recovery in Coronary Heart Disease Patients (ENRICHED). He has published and presented papers at various national meetings on cardiovascular psychophysiology, and clinical research in behavioral medicine. He has promoted evidence-based behavioral medicine and the importance of rigorous application of randomized clinical trial methodology for evaluating the effectiveness of behavioral interventions for mental disorders and behavioral risk factors for somatic illnesses.

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Faculty

Francis J. Keefe
Professor
Pain Prevention and Treatment Research Program
Box 3159
Duke University Medical Center
Durham, NC 27710

Phone: (919) 668-2806

Fax: (919) 668-2850

E-mail: keefe003@mc.duke.edu

Francis J. Keefe is a Professor of Psychiatry and Behavioral Sciences and Associate Director for Research in the Duke Pain and Palliative Care Initiative at Duke University Medical Center and Professor of Psychology: Social and Health Sciences at Duke University. He received his undergraduate degree in psychology at Bowdoin College (B.A., 1971) and his Ph.D. in Clinical Psychology at Ohio University (Ph.D., 1975.) Following graduate school he completed a Post-Doctoral fellowship in the Psychophysiology Lab at Massachusetts Mental Health Center (Harvard Medical School) where he conducted research on clinical applications of EMG biofeedback. Frank has broad interests in behavioral and psychological aspects of pain and pain management. He is recognized for his research on pain coping and his controlled treatment outcome studies evaluating the efficacy of coping skills training interventions for persons suffering from persistent disease-related pain.

He has played a key role in the development of clinical pain services and pain research programs at Duke Medical Center. For 20 years he directed the Pain Management Program and was a leader in the development of Duke Medical Center's multidisciplinary pain programs (both out-patient and in-patient.) Frank has developed and refined a number of treatment protocols for persistent pain including spouse- and partner-assisted pain coping skills training interventions. After spending a year and a half on the faculty of his alma mater (Ohio University), Frank returned to Duke in the Fall of 1999 to take a position as Associate Director for Research in Duke's new Pain and Palliative Care Program. Frank is currently an Associate Editor for the Journal of Consulting and Clinical Psychology. He also serves as Secretary of the American Pain Society and Psychology Section Editor for the journal Pain. Frank is a fellow of the Division of Health Psychology and of the Society of Behavioral Medicine. He has been active in the Society of Behavioral Medicine and International Association for the Study of Pain. He has published over 140 papers, 42 book chapters, and 3 books on topics ranging from pain during mammography to the assessment of cancer pain. In recognition of his clinical research, Frank was recently awarded the Wilbert Fordyce Clinical Investigator Award at the American Pain Society. He has served on numerous NIH Study Sections including the Behavioral Medicine Study Section and is frequently asked to consult with NIH program staff and other government programs (e.g. Department of Labor.)

Dr. Keefe recently completed his term as an Associate Editor for Health Psychology. He has frequently served as a member of the Division 38 Scientific Program as a reviewer.

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Faculty

Sheryl F. Kelsey
University of Pittsburgh
130 DeSoto Street
Pittsburgh, PA 15261

Phone: 412-624-5157

Fax: 412-624-7397

E-mail: kelsey@edc.gsph.pitt.edu

Dr. Kelsey is a statistician in the Department of Epidemiology and Co-Director of the Epidemiology Data Center (EDC), Graduate School of Public Health, University of Pittsburgh. The EDC has a 20-year history and is made up of nearly 100 faculty, staff and students. She and her colleagues coordinate multicenter clinical trials and registries primarily in cardiology, also in liver transplantation, neurology, psychiatry and ophthalmology. Her career has focused on design, coordination and analysis of clinical trials, and she has served as Principal Investigator or Co-Principal Investigator for coordinating centers for a number of large National Institutes of Health multicenter clinical trials. For 9 years, she has taught a class in design of clinical trials. Enrollment is usually between 40 and 50. One assignment is a group project to design a clinical trial over the semester. To focus on methods, students are not judged on scientific rationale. The assignment assumes no financial constraints, but patient burden is a key consideration. For the last two years, she also taught a small class in "controversies in clinical trials." Based on student interests, one year the theme was alternative medicine and the other year behavioral trials. She has served on over a dozen Data and Safety Monitoring Boards for the National Institutes of Health, the Veteran's Administration and Industry.

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Faculty

Genell L. Knatterud
Chairman of the Board and Chief Executive Officer
Maryland Medical Research Institute
600 Wyndhurst Avenue
Baltimore, MD 21210

Phone: 410-435-8139

Fax: 410-123-8622

E-mail: gknatterud@mmri.org

Dr. Genell Knatterud is currently Chairman of the Board and Chief Executive Officer of the Maryland Medical Research Institute and Chairman of the Board of Clinical Trials & Surveys Corp. in Baltimore, Maryland. She has a visiting appointment in the Department of Epidemiology at the Johns Hopkins University School of Hygiene and Public Health and an adjunct appointment in the Department of Epidemiology and Preventive Medicine at the University of Maryland. She was Professor from 1973 to 1984 in the Division of Clinical Investigation in the Department of Epidemiology and Preventive Medicine at the University of Maryland and Acting Director of the Division from 1980 to 1984. She was awarded a Ph.D. in Biometry from the University of Minnesota School of Public Health.

Dr. Knatterud has more than thirty years' experience in Coordinating Center activities for multicenter trials and observational studies. She has served as the Principal Investigator or Co-Investigator in the Coordinating Center for ten long-term multicenter trials supported by the National Institutes of Health and for eight trials supported by drug company sponsors.

Dr. Knatterud was a member of the Board of the Society for Clinical Trials, served as Program Chair for two annual meetings and as President for one term. She chaired the Subcommittee of the Policy Committee appointed to discuss issues of data integrity and auditing; the Subcommittee published a Position Paper in the Controlled Clinical Trials in 1998.

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Faculty

Beryl A. Koblin
Laboratory of Epidemiology
The New York Blood Center
310 E. 67th Street
New York, NY 10021

Phone: (212) 570-3105

Fax: 212-570-3385

E-mail: bkoblin@nybc.org

Beryl A. Koblin, Ph.D. is an epidemiologist and Associate Member in the Laboratory of Epidemiology of the New York Blood Center and an adjunct faculty member at the Columbia University Joseph L. Mailman School of Public Health. For over a decade, Dr. Koblin has conducted community-based studies of the epidemiology of HIV infection among various populations, including injection drug users, gay men and women at risk through heterosexual contact. These studies have led to conducting large-scale clinical trials of HIV vaccines and behavioral interventions. Dr. Koblin's work has been funded by grants and contracts from the National Institutes of Health, Centers for Disease Control and Prevention and private foundations.

Within the HIV Network for Prevention Trials, a national network for studying HIV prevention strategies, Dr. Koblin served as co-chair of the Behavioral Science Direction Group, was a member of the Scientific Steering Group and co-chaired several protocols. In New York, Dr. Koblin has served as an advisor to the New York State AIDS Institute regarding evaluation of HIV prevention programs and was a member of the CDC-mandated Prevention Planning Group for the New York State Department of Health.

Dr. Koblin received her Sc.M and Ph.D. in Epidemiology with a concentration in infectious diseases from the Johns Hopkins University School of Hygiene and Public Health.

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Faculty

Helena Chmura Kraemer
Professor of Biostatistics in Psychiatry
Department of Psychiatry and Behavioral Sciences
MC5717, 401 Quarry Road
Stanford, CA 94305

Phone: 650-723-7217

E-mail: hck@stanford.edu

Dr. Kraemer did her undergraduate work in mathematics at Smith College, completed a Fulbright year at Manchester University, England in the Statistics Department, and received her Ph.D. in Statistics from Stanford University. Because of her interest specifically in the behavioral aspects of medicine, she joined the staff and later faculty of the Department of Psychiatry and Behavioral Sciences in 1964, and has been Professor of Biostatistics in Psychiatry since 1986. With the growing importance of behavior in other fields of medicine, she teaches and consults extensively, not only with psychiatrists and psychologists, but in cardiology, pediatrics, oncology etc., including many randomized clinical trials (RCTs).

Teaching and consultation aside, her own research interests were initially on the reliability and validity of diagnosis and measurement, how to assess these qualities (in particular the intraclass correlation coefficient and kappa), how to improve these qualities for clinical and research purposes, and understanding of the impact these qualities have on the overall quality of research studies. This led to an interest in statistical power, and in particular, how to increase statistical power without necessarily increasing sample size. Medical test evaluation, particularly using signal detection methods (ROC) has been a more recent and continuing interest. Finally in the last few years, she has focused on risk research, including defining how risk research influences the conceptualization and design of RCTs, and the importance after completed RCTs of identifying on an exploratory basis the moderators and mediators of treatment.

She served as chairman of the Research Steering Committee of the Infant Health and Development Program, the first multi-site RCT of a behavioral intervention in low birth-weight premature infants, and as principle statistician of the MTA, a recent multi-site RCT comparing use of medication and psychotherapy alone and in combination for the effectiveness of treatment children with ADHD. She has been a member of several Data Safety and Monitoring Boards, e.g., at NIM and in the Veteran's Administration system. Thus she has had experience in RCTs from a variety of perspectives.

Dr. Kraemer serves on several editorial boards, in psychiatry (Archives of General Psychiatry), in psychology (Psychological Methods), and in statistics (Statistics in Medicine), and is a frequent reviewer for many journals in a variety of fields.

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Faculty

Nancy Houston Miller
Med/Cardiovascular Medicine
Stanford University
780 Welch Rd. #106
Stanford, CA, 94305-5735

Phone: (650) 725-5008

Fax: (650) 723-6798

E-mail: nhm@leland.stanford.edu

Nancy Houston Miller is the Associate Director of the Stanford Cardiac Rehabilitation Program and adjunct clinical assistant professor at the University of California San Francisco (UCSF) School of Nursing. With 25 years experience, her responsibilities include directing major clinical research trials in prevention and cardiac rehabilitation as well as training nurses and other health care professionals in this field. Nancy attended the University of Washington School of Nursing where she received her Bachelor of Science degree.

Ms. Miller is a past Chairman of the Board of the California Affiliate of the American Heart Association and served on the National Board of Directors of the Heart Association. She is a co-founder and past Chairman of the Lipid Nurse Task Force, (now the Preventive Cardiovascular Nurses Association), a national organization dedicated to training and expanding the role of nurses in cardiovascular risk reduction. Since 1995 she has represented the American Nurses Association on the National High Blood Pressure Education Program Coordinating Committee at the National Heart Lung and Blood Institute. In 2000 Nancy received the American Heart Association's Award of Meritorious Achievement for her work in secondary prevention and the Award of Excellence from the American Association of Cardiovascular and Pulmonary Rehabilitation for her contributions to the field of cardiopulmonary rehabilitation.

She is one of the developers of the MULTIFIT program, a nurse case management system for cardiovascular risk reduction and chronic diseases such as heart failure. The author of over 100 publications including both articles and book chapters in the areas of exercise training, smoking cessation, lipid management, hypertension, compliance, and the psychological recovery of post-myocardial infarction patients, she has also co-authored a book entitled "Lifestyle Management for Patients with Coronary Heart Disease".

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Faculty

Lynda H. Powell
Associate Professor
Rush-Presbyterian-St. Luke's Medical Center
Department of Preventive Medicine
Suite 470
1700 W. Van Buren Street
Chicago, IL 60612

Phone: (312) 942-2013

Fax: 312-563-2205

E-mail: lpowell@rush.edu

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Faculty

Michael A. Proschan
Office of Biostatistics Research
NHLBI
II Rockledge Center, Room 8222
6701 Rockledge Drive, MSC 7938
Bethesda, MD 20892-7938

Phone: (301) 435-0439

Fax: 301-480-1862

E-mail: ProschaM@nhlbi.nih.gov

Dr. Proshan was born December 23, 1958 in Palo Alto, California. His wife, Maria, and I have been married for 19 years, and I have 2 sons, Daniel (9) and Andrew (5). He is a National Master in the United States Chess Federation and enjoys basketball and other sports.

He received a Ph.D. in Statistics from Florida State University in 1989, an M.S. in Statistics from Stanford University in 1982, and a B.S. in Statistics and Mathematics (double major) from Florida State University in 1980.

Since 1989 he has been a Mathematical Statistician at the National Heart, Lung, and Blood Institute. He has worked on several clinical trials that used behavioral or non-pharmacologic interventions such as diets and lifestyle changes. His role in these trials is to help with design (sample size/power, whether to pair-match, whether to use a parallel-arm or crossover trial, etc.) and analysis issues (what kind of model to use, handling missing data, etc.). He is also involved in smaller clinical trials and other kinds of studies, such as measuring agreement between real time 3D echocardiography and angiography with respect to whether segments of the heart are diseased. His duties also include methodological research, and he has a special interest in research on adaptively modifying sample size in clinical trials.

He taught statistics and mathematics courses at Palm Beach Junior College, Tallahassee Community College, Florida State University and Stanford University. More recently, he taught a course called Methodology in Clinical Trials for the Foundation for the Advancement of Education in the Sciences.

Before becoming involved in biostatistics, he was an Engineering Statistician at Pratt and Whitney Aircraft, which makes engines for commercial and military airplanes. He conducted risk analyses, modeled failure times, and worked on tolerance problems, among other duties.

Dr. Proshan was also an Expert Witness for the Defense at the trial of Florida State University vs. Sylvia Huegli. The defendant was accused of cheating on a multiple choice exam, and the evidence presented was primarily statistical. She was found not guilty by the Florida State University Supreme Court.

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Faculty

Nina R. Schooler
Director
Psychiatry Research
Hillside Hospital Division NSLIJ Health System
Lowstein Research Building
76th Avenue and 266th Street
Glen Oaks, NY 11004

Phone: (718) 470-8161

Fax: 718-343-1659

E-mail: schooler@lij.edu

Nina Schooler is the Director, Psychiatry Research at Hillside Hospital Division of the North Shore Long Island Jewish Health System. She received her Ph.D. from Columbia University in social psychology in 1969. She held a number of positions in the Extramural Programs of the National Institute of Mental Health (NIMH) where she administered grant programs and grant review but also designed, directed and coordinated multi-center clinical trials of both medication and psychosocial treatments for schizophrenia. She left the NIMH to become Professor of Psychiatry at the University of Pittsburgh School of Medicine. She has continued to focus her research on both schizophrenia and multi-center trials at the University of Pittsburgh and more recently at Hillside Hospital where she is the Associate Director of an NIMH supported Intervention Research Center for Schizophrenia.

Her contributions to clinical trial methodology include instrument development for assessment of adverse effects, social adjustment and psychopathology. She has edited books and written about controlled clinical trials in clinical psychology and psychiatry. She has also been an active participant in the ongoing developments designed to enhance protection of potentially vulnerable populations who participate in research and is actively developing methods to assess patient understanding of research participation.

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Faculty

Sherry Willis
Pennsylvania State University
S 110 Henderson Building
University Park, PA 16802-6504

Phone: (814) 863-9735

Fax: (814) 863-4776

E-mail: slw@psu.edu

Dr. Sherry Willis is Professor of Human Development at The Pennsylvania State University. She received her Ph.D from the University of Texas at Austin in Educational Psychology. She is a Fellow in Divisions 15 and 20 of the American Psychological Association and in the Gerontological Society of America. She has served as President of Division 20 (Adult Development and Aging) of APA. In 1995 she was a Fulbright Scholar in Sweden. She is the co-author of a textbook Adult Development and Aging, now in its fifth edition. In 1999 she edited a book on Midlife Development. She is a co principal investigator on the Seattle Longitudinal Study with Dr. K. Warner Schaie as investigator. Dr. Willis' research focuses on changes in cognitive functioning in adulthood and aging. Much of her research has focused on the modifiability of cognitive functioning in old age through behavioral training programs. Currently she is the PI of one of six sites of a clinical trial examining the effectiveness of three cognitive interventions on enhancing cognitive functioning with cognitively demanding tasks of daily living as the primary outcome. Dr. Willis has developed measures of cognitively demanding tasks of daily living for nondemented and early stage Alzheimer elderly, and has studied longitudinal changes in everyday problem solving in both normal and demented elderly.