Biostatistics and Epidemiology

RESEARCH AND TRAINING DETAILS
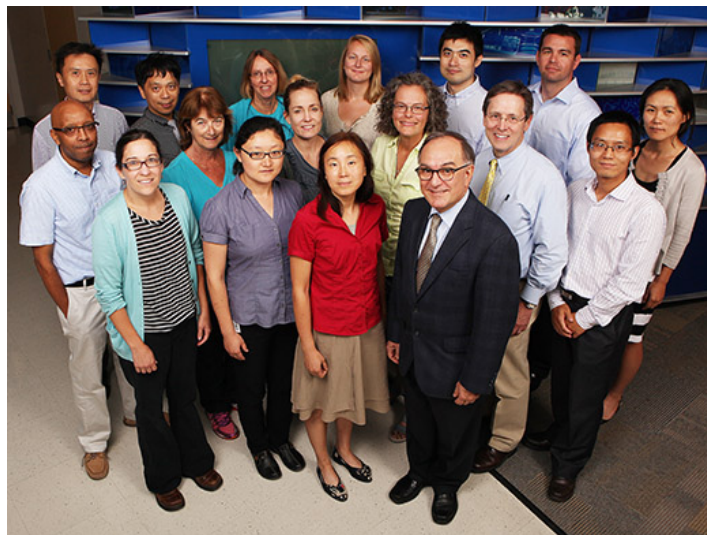
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Faculty	**22**
Joint Appointment Faculty	**14**
Research Fellows	**1**
Research Students	**12**
Support Personnel	**56**
Direct Annual Grant Support	**$3,733,222**
Peer Reviewed Publications	**138**

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Research Highlights

Our Research and Education Efforts

Biostatistics and Epidemiology faculty and staff contributed to 138 scientific articles. Collaborative papers ranged across all pediatric subspecialties: 23 were published in journals with an impact factor of 5.0 or higher and 12 involved the development or application of novel quantitative methods. The Division of Biostatistics and Epidemiology (DBE) faculty or staff were first authors of 18 and senior authors of 14. We participated in 135 active research grants and contracts, with annual direct costs totaling $42M (DBE direct costs: $3.4M).

Faculty members led independent research in statistical methods development and application and in areas of epidemiologic research. Examples include the biostatistical core of the NIH grant "Hemorrhagic & Ischemic Stroke Among Blacks & Whites," led by Jane Khoury, PhD; the PCORI grant "Propensity Score-based Methods for CER Using Multilevel Data: What Works Best," led by Mi-Ok Kim, PhD; the March of Dimes Social and Behavioral Sciences Research Grant entitled "Early Language and Functional Expectations (LIFE) Study of Infants and Toddlers with Hearing Loss," led by Jareen Meinzen-Derr, PhD; and the NIH grant "Neurobehavioral and Neuroimaging Effects of Traffic Exposure in Children," led by Patrick Ryan, PhD, MS.

Jessica Woo, PhD, associate professor in the Division of Biostatistics and Epidemiology within the UC Department of Pediatrics, and Elaine Urbina, MD, of the Heart Institute's Division of Preventive Cardiology, were awarded a $13.5 million five-year grant from the National Heart, Lung and Blood Institute entitled, "Childhood Cardiovascular Risk and Adult Cardiovascular Disease Outcomes: An International Long-term Follow-up (R01 HL121230)." The goal is to better understand how cardiovascular risk factors measured in children may influence the risk of developing adult-onset cardiovascular disease. This project represents the first time that this fundamental lifecourse question can be addressed and has the potential to identify critical childhood periods related to cardiovascular disease risk.

The project plans to follow up as many as 40,000 people who participated as children in seven studies that began in the 1970s and 1980s, including five U.S. studies and one each in Australia and Finland. Each of these studies measured cardiac risk factors in childhood and tracked the participants' health into adulthood. Two of the seven studies are based in Cincinnati and will be followed up by Drs. Woo and Urbina. One involved over 2,500 children from the Princeton City School District near Cincinnati who were as young as 6 when the study was conducted from 1973-76. At an adult follow-up between 1998-2003, when participants were an average of 36 years old, 17 cases of cardiovascular disease were already detected, with childhood risk factors identified even for that small subset. The other project is the NHLBI Growth and Health Study of 871 girls who were enrolled at age 9 or 10 and followed annually until their late 20s, and who are now in their early 40s. This group will be important in identifying early-onset heart disease.

The historical and newly collected data from this study will be harmonized and distributed by the International Childhood Cardiovascular Cohorts (i3C) Consortium, which is comprised of the seven cohorts included in this grant. The data will become available to the scientific community, extending the impact of this important grant.

DBE faculty taught in the Colleges of Medicine, Pharmacy, and Arts and Sciences, and in the MS program in clinical science sponsored by the CCTST. The Graduate Statistics Internship Program led by Bin Huang, PhD, and Siva Sivaganesan, PhD, UC Department of Mathematical Sciences, provided opportunities for PhD students and was beneficial to research projects in eight divisions at Cincinnati Children's. During FY2015, five graduate students participated in the program. In addition, we take responsibility for mentoring post-doctoral fellows in pediatrics and environmental health, and we are developing a curriculum for post-doctoral fellowships focused on epidemiology and biostatistics in pediatrics. We selected the first fellow in the summer of 2013: Samrat Yeramemeni, PhD, who is a clinical epidemiologist interested in examining the effect of obesity on functional and psychological outcomes in adult onset stroke and neonatal brain injury and subsequent neurological development. Richard Ittenbach, PhD, PSTAT, led the work of the CCTST in empirical bioethics, facilitating the development of this field across the UC academic medical center.

Strategic Planning and Capacity Building

With technical assistance by the Department of Learning and Organization Development, a five-year strategic destination plan to guide the Division of Biostatistics and Epidemiology (DBE) has been developed. Within the division, it is recognized that a primary mission of the division is to support collaborative research: our main five-year goal is to transform the current service-based collaborative model to one that promotes research partnership and leadership. Initiatives in this area are to develop and strengthen collaborative relationships among DBE faculty and staff; to strengthen collaborative research partnerships with other divisions; and to take a leadership role in Cincinnati Children's community-

based research initiatives. Another important mission of the division is education: the division's main five-year goal is to provide diverse educational opportunities in the areas of epidemiology, biostatistics and data management. Initiatives in this area are to promote continuing education and professional development of DBE faculty and staff; to provide formal and informal training opportunities for students (e.g., fellowships, internships); and to identify opportunities for our division to teach within Cincinnati Children's and UC. A third major five-year goal is to develop and optimize the capacity, financial resources, and operation efficiency of DBE. Initiatives in this area are to strengthen the capacity of the division through career development and strategic growth; to acquire and ensure adequate resources to continue the growth of the division's research and service activities; and to improve the operational effectiveness of the division by review and utilization of existing resources and infrastructure. DBE's fourth five-year goal is to increase the understanding and application of population science and quantitative methods throughout all facets of clinical research: within the academic health center, within the broader scientific community, and in the general public.

Research Infrastructure Development

The division's Data Management Center (DMC) supported approximately 90 studies in FY15, up from 75 in FY14. The DMC assists with grant application and protocol review, budgeting and resourcing for data management, case report form design, database development, data entry and documentation, discrepancy management, data cleaning and preparation for analysis. Rachel Akers, MPH, and Cyndie Baker, managers of DMC operations, lead a staff of seven clinical research data specialists, two clinical research database developers, five data coordinators and one data assistant. Matthew Fenchel, MS, oversees eight SAS programmers. DMC staff participate in continuing education programs and are active in professional societies: five are certified clinical data managers, five are SAS certified base programmers, two are SAS certified advanced programmers and two are certified Medidata Rave study builders. The staff now have seven active projects in Medidata Rave, the state-of-the-art clinical data management system Cincinnati Children's acquired in FY13, with two more funded projects set to begin. Process maps and training videos were added to accompany the twelve standard operating procedures (SOP) that govern DMC data management processes and are being adopted throughout Cincinnati Children's. The DMC is also leading efforts in case report form standardization, process instructions and templates, data quality in registries and SAS programming standards.

The Biostatistical Consulting Unit (BCU) supported 187 projects in 35 Cincinnati Children's divisions and two UC departments in addition to those housed at Cincinnati Children's. The BCU expedites access to statistical consulting and collaboration at Cincinnati Children's. It collaborates closely with the DMC, the Department of Biomedical Informatics and with the CCTST as part of "Research Central." Mekibib Altaye, PhD, director, and Matthew Fenchel, MS, manager, lead a staff of ten statisticians and procure the support of other DBE faculty and staff members depending on the expertise needed. The BCU has expertise in study design (including sample size estimation and power), grant and protocol preparation, statistical analysis, program validation, manuscript preparation and education. Specialized areas include meta-analyses, statistical process control, pharmacokinetics modeling and spatial-temporal modeling.

The Scale Development Unit (SDU) led by Richard Ittenbach, PhD, PSTAT, assists investigators with the creation and validation of new measures for use in medical settings. During FY 2015, the SDU collaborated with investigators on 34 different research projects from 25 different divisions/institutes at Cincinnati Children's and UC. Faculty and staff of the SDU consulted on a wide range of measurement related projects from decisional support (James M. Anderson Center for Health Systems Excellence) to cardiac rehabilitation and stroke (UC Physical Therapy) to sexually transmitted diseases (Division of Adolescent and Transition Medicine). In addition, SDU faculty coordinated an international conference on genomics and ethics in research and medical decision-making that brought together clinicians and scholars from around the globe to discuss difficult ethical issues confronting healthcare professionals today.

Maurizio Macaluso, MD, DPH, Professor and Director

Dr. Macaluso continued to lead the expansion of the division by strengthening its infrastructure and recruiting new faculty.

The Data Management Center (DMC) grew in FY15: the DMC further implemented its SOPs and related training opportunities, leading to adoption of the SOPs throughout the Cincinnati Children's, and supported 90 research projects throughout the institution, up from 75 in FY14. The Biostatistics Consulting Unit was established in 2012 to expedite access to biostatistical consulting and collaboration at Cincinnati Children's and continued to grow in FY15, supporting 187 projects in 35 Cincinnati Children's divisions and two UC departments in addition to those housed at Cincinnati Children's. Dr. Macaluso led the strategic planning process and the response to the Scientific Advisory Council (SAC) review of 2014. In FY15 Dr. Macaluso published five peer-reviewed articles and submitted seven abstracts. Of note is a paper published in the *Journal Cancer Prevention Research* (Piyathilake CJ, Macaluso M, Chambers MM, Badiga S, Siddiqui N, Bell W, Edberg JC, Partridge EE, Alvarez RD Johanning GL: **Folate and vitamin B12 may play a critical role in lowering the HPV 16 methylation associated risk of developing higher grades of cervical intraepithelial neoplasia.***Cancer Prev Res* (Phila) 2014; 7:1128-37), which presents new evidence that micronutrients associated with the one-carbon metabolic pathway reduce the risk of neoplastic progression in the cervix of women infected with high-risk human papillomavirus. Dr. Macaluso is director of the Biostatistics, Epidemiology, and Research Design Core of the NIH-funded Center for Clinical and Translational Science and Training (CCTST). During FY15 he participated in the submission of six applications for research funding, including the competitive renewal of the Clinical and Translational Science Award that supports the CCTST. In addition to providing guidance and advice to the DBE faculty, Dr. Macaluso mentors postdoctoral fellows and junior faculty in other Cincinnati Children's divisions.

Mekibib Altaye, PhD, Professor

In 2014-2015, Dr. Altaye published nine peer-reviewed articles and submitted eight abstracts. He is actively participating as a co-investigator and collaborator in six NIH funded projects, and he participated in the submission of five new grant applications. His research focuses on statistical modeling of correlated data particularly data generated from fMRI and MRI experiments. He closely collaborated with researchers from the Pediatric Neuroimaging Research Consortium (PNRC) in which he is one of the primary faculty members. Dr. Altaye serves as the director of the newly created Biostatistics Consulting Unit (BCU) within our division which aims to serve as a portal and facilitate access of researchers to the biostatistical and epidemiological expertise they need. Dr. Altaye continues to mentor staff, junior investigators, trainees and students in multiple academic units.

Katherine Bowers, PhD, Assistant Professor

In 2014-2015, Dr. Bowers published six peer-reviewed articles and submitted three abstracts. Dr. Bowers' research interests include the epidemiology of autism spectrum disorders and the impact of maternal exposures in pregnancy on maternal and child health. Her research has led to publications in prestigious journals and has been recognized within Cincinnati Children's with a Place Outcomes Research Award and a Trustees' Award.

Lili Ding, PhD, Assistant Professor

In 2014-15, Dr. Ding published seven peer-reviewed research papers and submitted eight abstracts to national meetings. She is actively participating as a co-investigator and collaborator in five NIH funded researches, and she participated in more than ten new grant applications. Her research focuses on Bayesian statistics and its applications in biomedical research, including statistical genetics and population pharmacokinetics and pharmacodynamics (PK/PD). Dr. Ding was awarded a 2015 CCTST methods grant entitled Joint Admixture and Association Modeling with Bivariate Mixed Binary and Continuous Outcomes in Admixed Individuals. Dr. Ding has been actively involved in collaborative research with faculty members from Adolescent Medicine, Asthma Research, Human Genetics, and Anesthesia within the UC College of Medicine on the design, plan, statistical analysis and report of research studies. Dr. Ding serves as review editor for the *Journal of Frontiers in Genetics* and reviewer for the *Journal of Pediatric Research*, the *BioMed Research International*, and *PLOS ONE*. Dr. Ding mentors junior faculty, fellows and students in DBE and several other divisions within the hospital.

Shelley Ehrlich, MD, MPH, MSc, ScD, Assistant Professor

In 2014-2015, Dr. Ehrlich published six peer-reviewed research papers, submitted four abstracts, and presented at two national meetings and two international meetings. She organized and co-chaired two symposium sessions at the Society of Epidemiological Research, as well as the International Society of Environmental Epidemiology meeting in the past year. She is actively participating as a principal or co-principal investigator and collaborator in two funded grants (K12-BIRCWH and an international grant awarded by the Israeli Environment Health Fund), and has two grants pending review and she participated in four new grant applications. Her research has focused on environmental and reproductive and perinatal epidemiology, more specifically on the association between environmental exposures to endocrine disruptors such as bisphenol A (BPA) and phthalates and fertility and pregnancy outcomes. Her research has also focused on translational molecular epidemiology, to better understand the underlying mechanisms for the observed associations at the level of the population. She was the co-leader of a BPA and reproductive health working group at the National Institute of Environmental Health Sciences (NIEHS). Dr. Ehrlich is also on the editorial board for the peer-reviewed journal *Fertility and Sterility*. Recently, she was voted president-elect of the Women's Faculty Association (WFA) at Cincinnati Children's where she is also currently participating is an Emerging Leadership Program.

Lin Fei, PhD, Associate Professor

In 2014-2015, Dr. Fei published two peer-reviewed research papers, submitted eight abstracts, and presented at one national meeting. He is actively participating as a co-investigator and collaborator in two NIH funded researches, and he participated in three new grant applications. Dr. Fei has been actively involved in collaborative research with faculty members from the Division of Gastroenterology, Hepatology and Nutrition, Division of Critical Care Medicine, and the Cancer and Blood Diseases Institute. His research interests include clinical trial designs, categorical data analysis, probability models in ranking and selection. Dr. Fei continues his volunteering at the University of Cincinnati's annual high school science and engineering expo as a judge, and as a proctor and grader at the annual Ohio Mathematics contest at Wright State University. He maintains active membership in several professional societies, and serves as a reviewer for journals and research funding organizations.

Md Monir Hossain, PhD, Associate Professor

In 2014-2015, Dr. Hossain published six peer-reviewed journal articles and submitted four abstracts. He participated in four grant submissions as a co-investigator and initiated one grant submission as a principle investigator. His research focuses on spatial and spatio-temporal statistics for point process and area level data. The applications involve the datasets generated from childhood cancer incidences linking with the environmental pollution; hospital utilization records with cost information; eye-tracking data for autistic children; and asthma exacerbations linking with the demographic, environmental and utilization cost information. Dr. Hossain serves as a lead statistician for the Division of Anesthesia, and mentors student and staff in various roles. He continues with his membership to the International Statistical Institute (ISI), The Netherlands.

Bin Huang, PhD, Professor

In 2014-2015, Dr. Huang published sixteen peer-reviewed articles and gave one presentation at a national conference. Dr. Huang's methodological research aims to develop/enhance methodologies for statistical causal inference, mediation analysis, modeling of health disparity and pubertal development. She is active in NIH-funded research, and she participated in the submission of nine NIH grant applications as principal investigator, co-investigator or statistical mentor. Dr. Huang continues to mentor staff, junior investigators and trainees in multiple academic units, and leads an internship program developed in collaboration with the UC Department of Mathematics. She also serves as a special panel reviewer for NIDA secondary data analyses RFA.

Richard Ittenbach, PhD, Professor

In 2014-2015, Dr. Ittenbach published three peer-reviewed articles and submitted four abstracts for professional

presentations. Of particular importance is his publication on development of clinical data management standard operating procedures for use in academic medical centers (Ittenbach, R. F., Baker, C.L., Corsmo, J. J. (2014)), and development of a quality assurance review process of clinical data management standard operating procedures in an academic medical center (*Acad Med, 89*(5), 745-748). The process began with a group of 16 practicing clinical data managers tasked with developing standard operating procedures (SOP) for clinical research. The SOPs were then evaluated by a team of eight senior faculty and research professionals, reworked and re-evaluated, and then evaluated by a team of three national clinical data management experts. These experts evaluated the SOPS using both academic and industry standards, and were asked to evaluate the SOPs against national, good clinical data management practice (GCDMP) guidelines. Dr. Ittenbach continues to advise groups such as the U.S. Department of Labor, the Society of Clinical Data Management, and the Association of Clinical and Translational Statisticians on the training and development of clinical data managers as well as the interface between data management and biostatistics.

Jane Khoury, PhD, Professor

In 2014-2015, Dr. Khoury published eleven peer-reviewed articles, collaboratively submitted over fifteen abstracts and she presented at national and international meetings. Her research focuses on diabetes, obesity and cardiovascular disease and stroke. She serves as the principal investigator of the biostatistical core for Special Program of Translational Research in Acute Stroke, currently completed three clinical trials, one still ongoing, a registry and a completed basic science project. She is also PI of a Cincinnati Children's sub-contract to UC for the stroke epidemiology R01. Dr. Khoury is a co-investigator on five other NIH-funded projects and in 2014 participated in the submission of sixteen new grant applications. She continues to mentor staff, junior investigators and trainees in multiple academic units, and is the lead instructor for classes in the UC Department of Environmental Health, where she holds a secondary appointment. She also has a joint appointment in the Division of Endocrinology within the UC College of Medicine, collaborates with many of the faculty and fellows, and serves on the division scholarly oversight committee.

Mi-ok Kim, PhD, Associate Professor

In 2014-2015, Dr. Kim published five peer-reviewed articles and submitted four abstracts. Dr. Kim's methodologic research focuses on causal inference and longitudinal and survival data analysis, for which she is supported by a K-award by the Agency for Healthcare Research and Quality and a Improving Methodology award by the Patient-Centered Outcomes Research Institute. She is also interested in innovative clinical trial designs, on which topic she has a LOI for extramural funding pending for review as a PI. In 2014 Dr. Kim participated in the submission of three new grant applications. Dr. Kim continues to mentor staff, junior investigators and trainees in multiple academic units.

Eileen King, PhD, Associate Professor

In 2014-2015, Dr. King published eight peer-reviewed articles and five abstracts. Her research focuses on outcomes research, digestive health, obesity and cardiovascular diseases. She serves as a faculty statistician for the James M. Anderson Center for Health Systems Excellence, the Heart Institute Research Core, and the Digestive Health Center. She serves as a statistician on eight NIH-funded projects and participated in the submission of twelve new applications as co-investigator and/or statistician. Dr. King submitted a U01 Administrative Coordinating Center application as the co-PI for the NHLBI Bed to Bassinet Program. She also provides faculty leadership of data coordination efforts for three multi-institutional collaborative networks in the areas of irritable bowel disease, pediatric cardiovascular disease, and pediatric obesity. Dr. King is a member of the Scholarly Oversight Committee for cardiology fellows and the Digestive Health Center Executive Committee. She continues to mentor staff, junior investigators and trainees in multiple academic units. She is the lead instructor of "Statistical Principles for Clinical Research Studies" in the UC College of Pharmacy, where she holds an adjunct faculty position. Dr. King is the ASA Council of Chapters Representative for the Cincinnati Chapter and will begin service as an elected member of the Board of Directors for the American Statistical Association (ASA) in 2016. She is associate editor of the *Journal of Statistical Education*, and statistical reviewer for *Journal of Allergy and Clinical*

Immunology – In Practice. Dr. King has made five internal and one external presentation on topics in statistical principles, statistics education and data management and presents the statistical training module for the Core Clinical Research Training program which is held three times per year. Dr. King also coordinates the statistical review for the Pilot and Feasibility studies for the Digestive Health Center and provides statistical review for the Place Outcomes Research Awards.

Ping-I Lin, MD, PhD, Assistant Professor

In 2014-2015, Dr. Lin published four peer-reviewed journal articles. He participated in two grant submissions as a co-investigator and initiated six grant submissions as a principle investigator. His research interests have been focused on the identification of genetic variants associated with the risk of neurological and psychiatric diseases, such as bipolar disorder, Alzheimer's disease, schizophrenia, and autism. Particularly, Dr. Lin has been interested in research methods of dissecting genetic heterogeneity, endophenotypes, and paradoxical locus-trait associations. His publications in the past seven years have received nearly 965 citations. Dr. Lin has been actively involved in collaborative research with faculty members from the Division of Child and Adolescent Psychiatry at Cincinnati Children's within the University of Cincinnati College of Medicine and the Department of Psychiatry and Neurobehavioral Science at the UC College of Medicine. A study in press entitled "Correlations of tumor necrosis factor gene pathway, corticolimbic functional activity, and aggression in adolescents with bipolar disorder: a preliminary study", led by Dr. Lin, examined the relationships among genetic and neurobiological pathways to aggressive tendencies in pediatric bipolar disorder. He has been invited to present his pioneering work in the genetics of autism at the Texas Autism Research Conference. Dr. Lin also mentors graduate students and junior faculty members of other divisions. He is building a strong academic service record, maintaining active memberships in several professional societies, and serving as a reviewer for scientific journals in the area of human genetics and psychiatry, and is an editorial member of *World Journal of Psychiatry* and *Biomed Research International*. Dr. Lin also serves as a member of the Autism Treatment Network Scientific Review Committee, and was invited to attend the 12th Annual National Academies Keck Futures Initiative (NAKFI) Conference, Collective Behavior: From Cells to Societies, which is an exclusively invitation-based conference. Dr. Lin was invited to speak at the 2nd Annual Molecular Psychiatry Meeting.

Jareen Meinzen-Derr, PhD, Associate Professor

In 2014-2015, Dr. Meinzen-Derr published ten peer-reviewed articles (in print) and submitted over twelve abstracts. As part of her ongoing research, Dr. Meinzen-Derr and her research team have received funding from the March of Dimes to expand her current work on language and functional skill outcomes among children who are deaf or hard-of-hearing to infants and toddlers. In 2014, Dr. Meinzen-Derr became the Schmidlapp Woman Scholar at Cincinnati Children's Hospital Medical Center. With this award, she is transitioning her research towards the first necessary phase of developing language-based interventions using technology tailored to the cognitive level of children who are deaf or hard of hearing. Dr. Meinzen-Derr is dedicated to the mentoring of staff, junior investigators and trainees in multiple academic units. She contributes to the experimental design lectures in Neonatology and Developmental and Behavioral Pediatrics. She continues to be the primary instructor of "Introduction to Epidemiology" in the graduate program in Biostatistics and Epidemiology within the UC Department of Environmental Health, in which she developed an online curriculum for the same program and for the CCTST.

Nicholas Ollberding, PhD, Assistant Professor

In 2014-2015, Dr. Ollberding published five peer-reviewed research papers and submitted six abstracts. His publication conducted with fellow Cincinnati Children's and UC collaborators (Ollberding NJ, Couch SC, Woo JG, Kalkwarf HJ. **Within- and Between-Individual Variation in Nutrient Intake in Children and Adolescents**. *J Acad Nutr Diet*. 2014) is particularly noteworthy. For this study, the within- to between-individual variance ratios and number of 24-hour recalls required to rank-order children and adolescents on usual intake for select macro- and micronutrients was examined for participants in the

2007-2010 National Health and Nutrition Examination Survey (NHANES). It was found that a total of six to nine and three to six 24-hour recalls were typically sufficient to rank-order children and adolescents, respectively, on usual intake with an accuracy of r=0.8. Additional recalls were required to achieve the same accuracy for energy-adjusted nutrients. Variance ratios were similar for adolescents across racial/ethnic groups, but highly variable in children. This study provides important information for nutrition professionals and researchers, as it will allow them to better plan, conduct, and interpret studies utilizing this dietary assessment instrument. Dr. Ollberding serves as an associate editor for the journal *Public Health Nutrition* and is a member of the steering committee for the Nutritional Epidemiology Research Interest Section of the American Society for Nutrition. Since joining the DBE, Dr. Ollberding has also been involved in the mentoring a postdoctoral fellow conducting nutritional epidemiology research.

Patrick Ryan, PhD, Associate Professor

In 2014-2015, Dr. Ryan published nine peer-reviewed research papers, submitted three abstracts, and presented at two national/international meetings and conferences. Of note is a paper published in *Science of the Total Environment* (Ryan PH, Son SY, Wolfe C, Lockey J, Brokamp C, LeMasters GK. **A Field Application of a Personal Sensor for Ultrafine Particle Exposure in Children**. *Science of the Total Environment*. 2015;508:366-373) which describes the successful field test of a new sensor for personal ultrafine particle exposure to children. Dr. Ryan's research interests include air pollution epidemiology (focusing on respiratory and neurobehavioral outcomes in children) and exposure assessment. Dr. Ryan is currently the PI of two NIH-funded projects including studies of personal exposure to ultrafine particles in children with asthma and the association between early childhood exposure to diesel exhaust particles and neurobehavioral and neuroimaging outcomes in the CCAAPS cohort. In the past year Dr. Ryan also contributed to the UC Department of Environmental Health's training program as an instructor ("Design and Management of Field Studies in Epidemiology, Spring 2015) as well as serving as primary advisor to PhD and MS students.

Heidi Sucharew, PhD, Assistant Professor

In 2014-2015, Dr. Sucharew published nine peer-reviewed research papers. Dr. Sucharew's research focuses on stroke, epidemiology and clinical trials, and the impact of environmental exposures on child health, with methodology interest in latent variable modeling. She is one of the biostatisticians for the Greater Cincinnati and Northern Kentucky Stroke Team, and she continues to serves as co-director of the Biostatistical Core for the Special Program of Translational Research in Acute Stroke with a recent successful completion of the phase II combined approach to lysis utilizing eptifibatide and rt-PA in acute ischemic stroke full dose regimen clinical trial (Adeoye O, et al. Stroke. 2015). Dr. Sucharew mentors junior faculty, fellows and students in the Division of Biostatistics and Epidemiology and other divisions within the medical center. She has assisted in the development of and has served as the primary instructor of "Introduction to Biostatistics" online course and as an invited lecturer in the "Design and Management of Field Studies in Epidemiology" course in the graduate program in Biostatistics and Epidemiology in the UC Department of Environmental Health.

Rhonda Szczesniak, PhD, Associate Professor

In 2014-2015, Dr. Szczesniak published six peer-reviewed articles and collaborated on four abstracts. She directs the Pulmonary Biostatistical Core for the Division of Pulmonary Medicine. Her methodologic research interests are functional data analysis and semiparametric models with application to medical monitoring. She applies novel statistical methods to study outcomes of children with cystic fibrosis and obstructive sleep apnea. She is a biostatistical collaborator on three extramural awards, including six NIH-funded projects as two foundation awards. She also collaborates on several internal projects, and she participated in the submission of several new grant applications this year. Dr. Szczesniak applied for her own career development award (NIH/NHLBI K25) to enable her career development from statistician into clinical and translational researcher in quantitative biomedicine. She was PhD thesis advisor for a statistics student in the UC Department of Mathematics, and she continued to mentor junior faculty, staff and other students in multiple academic units. She was appointed as statistical editor to *Thorax*, which is the official journal of the British Medical Society. She was again

invited to serve as chair of the Biostatistics and Epidemiology Session for the North American Cystic Fibrosis Conference.

Jessica Woo, PhD, Associate Professor

In 2014-2015, Dr. Woo published ten peer-reviewed articles, was listed in the 67th edition of *Who's Who in America* and serves on the American Heart Association Atherosclerosis, Hypertension and Obesity in Youth subcommittee. Her research focuses on the developmental pathways leading to pediatric obesity and its comorbidities. Dr. Woo was awarded an NIH R01 as PI in 2014 examining the role of childhood cardiovascular risk factors in adult cardiovascular disease, through an international consortium of seven large cohorts. In addition, Dr. Woo led the biostatistics unit of the Heart Institute Research Core and continues to mentor staff, junior investigators and trainees in multiple academic units. She gives lectures on study design and biostatistical analysis to MD fellows and staff in the Heart Institute and lectures for "Introduction to Epidemiology" in the graduate program in Biostatistics and Epidemiology in the UC Department of Environmental Health, where she holds a secondary appointment.

Bin Zhang, PhD, Associate Professor

In 2014-2015, Dr.Zhang published ten peer-reviewed research papers and he submitted six abstracts. His research interests include clinical trials, survival analysis, longitudinal data analysis and optimal designs. Of note is the paper "Diagnostic Performance and Dose Comparison of Filtered Back Projection and Adaptive Iterative Dose Reduction Three-dimensional CT Enterography in Children and Young Adults", which investigated diagnostic performance and radiation dose with the use of computed tomographic (CT) enterography in children and young adults and compared reconstruction with filtered back projection (FBP) to that with adaptive iterative dose reduction (AIDR) with three-dimensional (3D) processing. We found that CT enterography is highly accurate for detection of active inflammation in pediatric patients and has excellent interreader reliability. Reduced-dose CT enterography with AIDR 3D allowed substantial dose reduction compared with that used with FBP CT enterographic examinations, while maintaining a high diagnostic performance. This article was published in *Radiology* which is the top journal in their specialty. Dr. Zhang was a sub-PI of an NIH funded R01 grant 'Mechanisms of Refractory Hypertension' and was involved in several other NIH funded studies.

Nanhua Zhang, PhD, Assistant Professor

Dr. Zhang joined the Division of Biostatistics and Epidemiology as assistant professor within the UC College of Medicine in August 2013. He is a statistician with interests in missing data, comparative effectiveness research, clinical trial design, and behavioral intervention. Dr. Zhang has been actively involved in collaborative research with faculty members from the Division of Pulmonary Medicine and Physical Medicine and Rehabilitation within the UC College of Medicine. In the past year, Dr. Zhang published eleven peer-reviewed research papers and submitted eight abstracts. Dr. Zhang serves as a peer reviewer for the *Journal of Royal Statistical Society*, *Biometrics*, *Statistics in Medicine*, *American Journal of Public Health*, and *BMC Medical Research Methodology*.

Significant Publications

Alexander ES, Martin LJ, Collins MH, Kottyan L, Sucharew H, He H, Mukkada VA, Succop PA, Abonia JP, Foote H, Eby MD, Grotjan TM, Greenler AJ, Dellon ES, Demain JG, Furuta GT, Gurian LE, Harley JB, Hopp RJ, Amir Kagalwalla, Kaul A, Nadeau K, Noel RJ, Putnam PE, von Tiehl KF, Rothenberg ME. Twin and Family Studies Reveal Strong Environmental and Weaker Genetic Cues That Explain High Heritability of Eosinophilic Esophagitis. *J Allergy Clin Immunol*. 2014, 134(5):1084-1092.

> This study, part of Dr. Alexander's dissertation research, quantified the influence of genes and environment on familial clustering of eosinophilic esophagitis (EoE). Analysis of the family history of 914 EoE probands and 2192 first-degree relatives and of data from an international registry of monozygotic and dizygotic twins revealed that the rate of EoE in first-degree relatives of a proband was about 2%. Recurrence risk ratios ranged from 10 to 64, depending on the family

relationship. In the nuclear family cohort, combined gene and common environment heritability was 72.0% ± 2.7%. In the twins cohort, genetic heritability was 14.5% ± 4.0% and common family environment contributed 81.0% ± 4% to phenotypic variance. Thus, nuclear-family heritability of EoE is high, but the twins cohort analysis revealed a powerful role for common environment compared with additive genetic heritability.

Bowers K, Wink LK, Pottenger A, McDougle CJ, Erickson C. Phenotypic Differences in Individuals with Autism Spectrum Disorder Born Preterm and at Term Gestation. *Autism*. 2015 Aug;19(6):758-63.

In this article we compared children with autism spectrum disorder (ASD) who were born preterm to children with ASD born term or later. We identified several co-occurring conditions that were more prevalent among the children with ASD born preterm including attention deficit hyperactivity disorder, seizure disorders, language impairment and sleep apnea. Children with ASD born preterm may represent a unique ASD phenotype. The findings are significant as they may have implications for understanding the underpinnings of a subset of individuals with ASD and contribute to the development of focused treatments for ASD among children born preterm.

Kang J, **Zhang N**, Shi R. A Bayesian nonparametric model for spatially distributed multivariate binary data with application to a multidrug-resistant tuberculosis (MDR-TB) study. *Biometrics*. 2014 Dec;70(4):981–92.

Two types of correlations are usually involved when studying spatially distributed multivariate binary data: the correlation between the multiple outcomes at one location and the spatial correlation between the locations for one particular outcome. We adopt a Bayesian nonparametric approach to jointly modeling multivariate spatial binary data by integrating both types of correlations. The proposed model was applied to a multidrug-resistant tuberculosis case study. Our analysis shows a strong correlation among isoniazid (INH), rifampin (RIF), and ethambutol (EMB) over space, implying that the resistance profiles of these three drugs are similar across the study region, while the correlation of streptomycin (SM) with other three drugs are low. This suggests that the SM could be an alternative when patients having high resistance to the other three drugs.

Nehus E, Liu C, Hooper DK, **Macaluso M**, **Kim MO**. Clinical Practice of Steroid-Avoidance Protocols in Pediatric Kidney Transplant recipients. *Am J Transplant*. 2015 Aug;15(8):2203-10.

Steroid-avoidance protocols have recently gained popularity in pediatric kidney transplantation. This study investigated the clinical practice of steroid avoidance and examined patient level and center level determinants of the practice. With all patient- and center-level factors adjusted for, the variation in practice between centers remained highly significant, which may reflect uncertainty about the safety and efficacy of steroid avoidance protocols. The results suggests not only the need of comparative effectiveness research (CER) to evaluate the safety and efficacy of steroid avoidance but also the need of addressing the inter-center practice variation in such research. In presence of practice variation across transplant centers CER using observational data may suffers from bias from confounding both at the patient and clinic/center level. This is common for any CER using structured observational data such as registry or research network data. The study is the first published one supported by the PCOR methodology development award that Dr. Kim is the PI. The PCOR methodology project aims to improve rigor and efficiency of statistical analysis.

Ryan PH, Son SY, Wolfe C, Lockey J, Brokamp C, LeMasters G. A field application of a personal sensor for ultrafine particle exposure in children. *Sci Total Environ*. 2015 Mar 1;508:366-73.

Research suggests that ultrafine particles (UFPs, particles Ie<100 nm in diameter) can be inhaled deep into the lungs and also directly transported to the brain. An important source of UFPs in urban areas is traffic, particularly diesel-powered trucks and buses. Accurately determining children's exposure to UFPs, however, is difficult due to the limited number of devices capable of measuring UFPs, the lack of accurate exposure models, and children's time-activity patterns. In this publication, Dr. Ryan and his colleagues measured UFP exposure among children with asthma using

a newly developed personal sensor with GPS technology. The results of the study show that the sensor can be worn by children and used to accurately determine the amount and location where UFP exposure occurs. The results of the study also show that children are exposed to significantly increased levels of UFPs while riding in cars and walking near traffic compared to levels in their homes. The study findings have led to an ongoing NIH-funded R21 grant to improve the sensor based on the children's feedback and deploy the revised sensor in a large epidemiologic study of children's exposure to UFPs and respiratory health.

Division Publications

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Faculty, Staff, and Trainees

Faculty Members

Maurizio Macaluso, MD, DrPH, Professor
Leadership Division Director; Co-Director, Biostatistics, Epidemiology and Research Design Core, UC Center for Clinical and Translational Science and Training

Research Interests Epidemiologic research methods; cancer epidemiology; occupational epidemiology; health effects of sexual, reproductive and contraceptive behavior; acceptability, efficacy and safety of contraceptive and assisted reproductive technology; infectious disease epidemiology; surveillance systems.

Mekibib Altaye, PhD, Professor
Leadership Director, Biostatistical Consulting Unit

Research Interests Design and analysis of correlated, clustered and longitudinal data; design and analysis of functional and structural brain image data and inference procedures for reliability data.

Katherine Bowers, PhD, Assistant Professor
Research Interests Perinatal epidemiology, maternal genetic and environmental exposures and offspring neurodevelopment including autism spectrum disorders.

Lili Ding, PhD, Assistant Professor

Research Interests Bayesian statistics and its applications in biomedical research, including statistical genetics, population pharmacokinetics and pharmacodynamics (PK/PD), latent variable modeling, and survival analysis.

Shelley Ehrlich, MD, MPH, MSc, ScD, Assistant Professor

Research Interests Environmental exposures to endocrine disruptors and perinatal and reproductive health outcomes; fetal programming of childhood diseases; molecular epidemiology (epigenetics, gene-environment interactions); global health.

Lin Fei, PhD, Associate Professor

Research Interests Clinical trial design and analysis; probability models in ranking and selection; categorical data analyses.

Md. Monir Hossain, PhD, Associate Professor

Research Interests Spatial and spatial-temporal point process and area level modeling; mixture models; inter-rater reliability; multi-level modeling; health services and outcomes research.

Bin Huang, PhD, Professor

Research Interests Mediation analysis; statistical causal inference; Bayesian statistics modeling.

Richard F. Ittenbach, PhD, Professor

Leadership Director, Scale Development Unit

Research Interests Development, validation and analysis of scales for measurement of biomedical and bio-behavioral factors.

Jane C. Khoury, PhD, Professor

Research Interests Epidemiology of stroke with special emphasis on childhood stroke and stroke in those with diabetes; the effect of intra-uterine exposure to type 1 diabetes on childhood growth, metabolism and cardiac function.

Mi-Ok Kim, PhD, Associate Professor

Research Interests Extension of propensity score methods to multilevel observational data and a high-dimensional big data setting, and use of quantiles to better depict the rate of decline in a key pulmonary functional measurement in cystic fibrosis patients; principle area of application is inflammatory bowel disease and cancer.

Eileen King, PhD, Associate Professor

Research Interests Design and analysis of clinical trials for health care and pharmaceutical research studies; comparative effectiveness research using clinical data from large multi-site registries.

Ping-I Lin, MD, PhD, Assistant Professor

Research Interests Genetic epidemiology; imaging genetics; pharmacogenomics; eye tracking tests; biostatistical methods focused on structural equation modeling; clustering algorithms and admixture analysis.

Jareen Meinzen-Derr, PhD, Associate Professor

Research Interests Hearing and deafness; developmental disabilities; neonatal outcomes.

Nicholas Ollberding, PhD, Assistant Professor

Research Interests The role of diet in the etiology and the survival of cancer; dietary assessment and analysis methodology; molecular epidemiology; gut microbial structure and function.

Patrick Ryan, PhD, Associate Professor

Research Interests Air pollution epidemiology and exposure assessment; pediatric respiratory health; neurobehavioral development; indoor air pollutants; and environmental exposure to elongated mineral fibers.

Shelia Salisbury, PhD, Professor Emeritus

Research Interests Design, analysis, and interpretation of results from clinical trials and observational studies.

Heidi Sucharew, PhD, Assistant Professor

Research Interests Stroke, epidemiology and clinical trials; environmental exposures and child health; structural equation modeling; latent profile analysis; latent variable modeling.

Rhonda Szczesniak, PhD, Associate Professor
Research Interests Biostatistical interests are functional data analysis applications, including self-modeling, semiparametric and nonparametric regressions. Epidemiologic interests include diabetes in pregnancy and outcomes research for children with cystic fibrosis and obstructive sleep apnea.

Jessica Graus Woo, PhD, Associate Professor
Research Interests Developmental pathways leading to pediatric obesity, and specific metabolic complications of obesity, such as insulin resistance and dyslipidemia.

Bin Zhang, PhD, Associate Professor
Research Interests Statistical methods in clinical trials, survival analysis, longitudinal data analysis and optimal designs.

Nanhua Zhang, PhD, Assistant Professor
Research Interests Missing data; comparative effectiveness; clinical trial design; meta-analysis; scale development; joint modeling; environmental health; community-based intervention; health disparity; behavioral intervention; health psychology.

Joint Appointment Faculty Members

Lilliam Ambroggio, PhD, Assistant Professor (Hospital Medicine)
Research Interests To improve the health of children through improved diagnostic methods for common serious infections.

Melinda Butsch Kovacic, MPH, PhD, Assistant Professor (Asthma Research)
Research Interests Environmental and community-based epidemiology; genetic, epigenetic, and environmental biomarkers of chronic disease with emphasis on asthma and cancer; assessment and symptom prevention via multimedia intervention approaches.

James Cnota, MD, Associate Professor (Cardiology)
Research Interests Multicenter trials in pediatric heart disease, fetal cardiology, perinatal outcomes in congenital heart disease.

Nancy Daraiseh, PhD, Assistant Professor (Center for Professional Excellence Research & EBP)
Research Interests Occupational health and safety; human factors; patient safety; health outcomes; stress.

Adekunle Dawodu, MD, Professor (Center for Global Child Health)
Research Interests Vitamin D and international child health outcomes.

Paul Horn, PhD, Professor (Neurology)
Research Interests Robust methods, simulation, and statistical computing. In particular, derivation of robust reference intervals (also known as reference ranges) and quantile estimators.

Donna Carlson Jones, PhD, Assistant Professor (Plastic Surgery)
Research Interests Bone development and shape, and how ontogeny, function, and evolution of craniofacial morphology influence disease states such as mandibular hypoplasia.

Long Lu, PhD, Assistant Professor (Biomedical Informatics)
Research Interests Using quantitative approaches to address fundamental questions in molecular biology and human diseases, in particular, deciphering the human genetic blueprint, modeling complex biological systems, and facilitating drug discovery and development.

Lisa J. Martin, PhD, Associate Professor (Human Genetics)
Research Interests Statistical genetics, statistical methods to improve genotype quality, obesity, cardiovascular genetics, allergic diseases.

Ardythe L. Morrow, PhD, Professor (Director, Center for Interdisciplinary Research in Human Milk and Lactation)
Research Interests Molecular epidemiology of human milk; epidemiologic methods; prevention of infectious disease; predictive biomarkers of neonatal outcomes.

Jennie G. Noll, PhD, Professor (Behavioral Medicine & Clinical Psychology)
Research Interests Developmental effects of childhood abuse; longitudinal methods; multivariate, dynamic modeling.

Sunghee Oh, PhD, Assistant Professor (Human Genetics)
Research Interests Temporal dynamic methods in gene expression profiles; bayesian inference of genetic regulatory networks; and statistical and computational methods on hierarchical structures on post transcriptional process.

James L. Peugh, PhD, Assistant Professor (Behavioral Medicine & Clinical Psychology)
Research Interests Cross-sectional, longitudinal, and multilevel latent variable mixture modeling; missing data handling; pedagogical manuscripts.

Chad E. Shenk, PhD, Assistant Professor (Behavioral Medicine & Clinical Psychology)
Research Interests Childhood maltreatment, psychological and physiological mediators of stress and trauma exposure, research design and methodology, and statistical modeling.

Trainees

- **Eileen Alexander, PhD**, 2011, Xavier University, Cincinnati, OH

- **Mohammad Bhuiyan, MS**, 2012, University of Cincinnati, Cincinnati, OH

- **Cole Brokamp, BS**, 2010, University of Cincinnati, Cincinnati, OH

- **Dan Li, MS**, 2011, Uppsala University, Sweden

- **Samrat Yeramaneni, PhD**, 2013, University of Cincinnati, Cincinnati, OH

- **Huaiyu Zang, MS**, 2012, University of Cincinnati, Cincinnati, OH

- **Yue Zhang, MS**, 2011, DePaul University, Chicago, IL

Grants, Contracts, and Industry Agreements

Biostatistics and Epidemiology

Grant and Contract Awards	Annual Direct

Bowers, K

The Impact of Home Visiting Services on the Prevention of Unintentional Injury during Early Childhood

Ohio Department of Public Safety

8/11/2014-6/30/2015	$37,481

Khoury, J

Comparison of Hemorragic and Ischemic Stroke Among Black and Whites

National Institutes of Health (University of Cincinnati)

R01 NS030678	7/1/2009-3/30/2016	$95,065

Recanalization Therapies and Markers of Stroke Outcome

National Institutes of Health(University of Cincinnati)

P50 NS044283	5/1/15-4/30/16	$30,695

Kim, M

Rigor of Multi-Registry CER Studies: Towards Patient-Centered Treatment Planning

Agcy for Healthcare Research and Quality

K18 HS022437	8/1/2014-7/31/2016	$125,505

Propensity Score-based Methods for CER Using Multilevel Data: What Works Best

Patient-Centered Outcome Research Inst.

ME-1403-13922	1/1/2015-12/31/2017	$269,274

Meinzen-Derr, J

Early Language and Functinal Expectations (LIFE) Study

March of Dimes

12-FY14-178	6/1/2015-5/31/2016	$78,169

Sucharew, H.

Multiple Risk Factors and Neurodevelopment Deficits in Rural Appalachian Children

National Institutes of Health(University of Cincinnati)

R21 ES021106	7/9/2012-6/30/2015	$13,419

Ryan, P

Neurobehavioral and Neuroimaging Effects of Traffic Exposure in Children

National Institutes of Health

R01 ES019890	7/1/2012-3/31/2013	$481,725

Assessing Personal Exposure to Ultrafine PM Number and Respiratory Health

National Institutes of Health

R21 ES024713	3/1/2015-2/28/2017	$149,858

Efficiency of HEPA Air Purification in Reducing Traffic-Related Particle Exposure

US Depart of Housing & Urban Development(University of Cincinnati)

OHHHU0027	12/1/2014-11/30/2016	$19,648

Woo, J/Urbina, E

Childhood CV Risk and Adult CVD Outcomes: an International Long-term Follow-up

National Institutes of Health

R01 HL121230	12/1/2014-11/30/2019	$2,432,383
	Current Year Direct	**$3,733,222**
	Total	$3,733,222

Early Escape Option Helps Balance Needs of Patients, Investigators

Bin Huang, PhD

Scientists designing crossover clinical trials, particularly those involving rare diseases, often must strike a delicate balance between maximizing the study's potential for discovery and minimizing patient exposure to ineffective treatment.

The Division of Biostatistics and Epidemiology partners with nearly all clinical and translational research programs at Cincinnati Children's to help them design studies and manage statistical analysis. Its faculty members also conduct direct studies to ensure and enhance the strength and innovation of research.

In a recent example of this work, a study published in July 2014 in *Contemporary Clinical Trials*, explored findings from previous work on treatments for the inflammatory disorder familial Mediterranean fever (FMF). The study's authors included first author Bin Huang, PhD, from Biostatistics and Epidemiology; senior author Philip Hashkes, MD, from the Shaare Zedek Medical Center in Israel; and colleagues from the Division of Rheumatology at Cincinnati Children's.
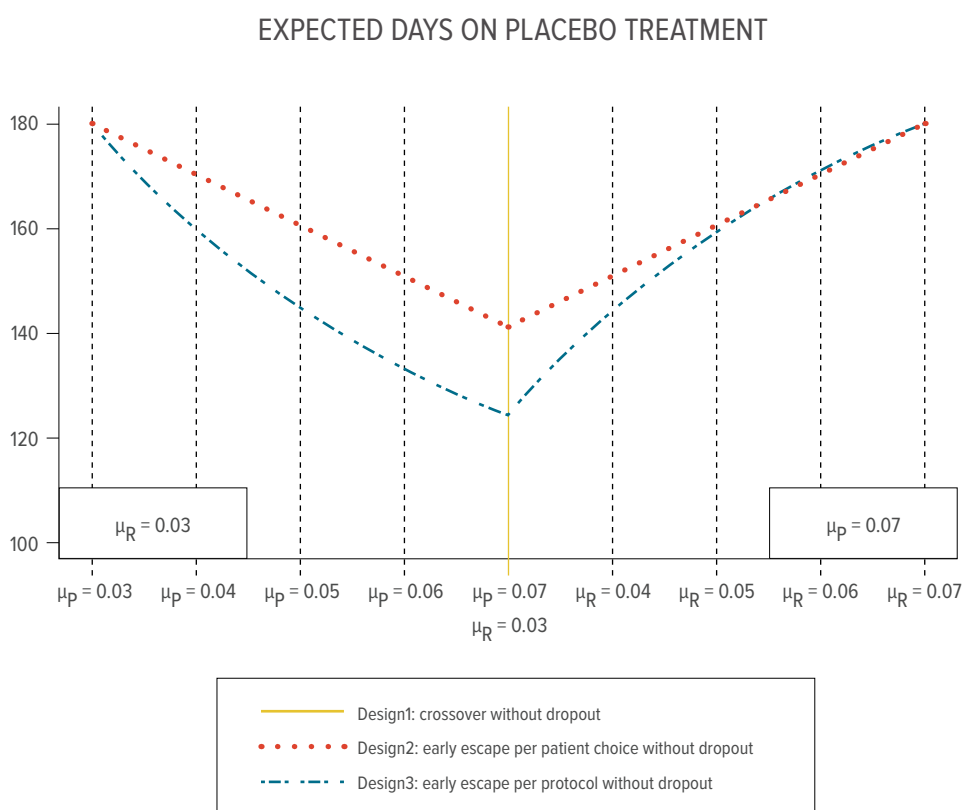
The team compared study power and dropout rates among three types of crossover trial designs: traditional without early escape, early escape as a patient choice, and early escape based on accepted protocol.

Both early-escape approaches were preferable to the traditional method. Researchers found that supporting exits based on patient choice reduced the dropout rate as much as 29 percent. However, the patient choice approach also increased patient exposure to the less effective treatment arm, which suggests that investigators must be mindful of the trade-offs between study design methods.

RESEARCH AND TRAINING DETAILS

Faculty	22
Joint Appointment Faculty	14
Research Fellows	1
Research Students	12
Support Personnel	56
Direct Annual Grant Support	$3.7M
Peer Reviewed Publications	138

Huang B, Giannini EH, Lovell DJ, Ding L, Liu Y., Hashkes P.J. Maximizing study power and minimizing patient exposure to ineffective treatment, *Contemporary Clinical Trials*, July 2014. V38(2): 204-212.

EXPECTED DAYS ON PLACEBO TREATMENT

Legend:
- Design1: crossover without dropout
- Design2: early escape per patient choice without dropout
- Design3: early escape per protocol without dropout

Expected time on placebo was calculated under the assumption of a Poisson distribution following the formula presented in Appendix A, with parameter settings similar to the familial Mediterranean fever (FMF) trial, i.e. a = 1, A = 5. Y axis shows the expected days on placebo; X axis corresponds to the rate of attack. The solid line corresponds to results of early escape per protocol; dashed line corresponds to the results of early escape per patient choice. Under the traditional crossover design without escape, the number of days on placebo treatment is 180 days.

Supporting exits based on patient choice reduced the dropout rate as much as 29 percent.