

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Shaffer, Michele L.		POSITION TITLE Senior Staff Biostatistician, Center for Clinical and Translational Research; Associate Director, Children's Core for Biomedical Statistics	
eRA COMMONS USER NAME (credential, e.g., agency login) MSHAFFER			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Penn State, University Park, PA	BS	05/96	Mathematics
Penn State, University Park, PA	MS	12/99	Statistics
Penn State, University Park, PA	PhD	12/02	Statistics

**A. Personal Statement**

I have participated in several clinical trials, including serving as the principal biostatistician and PI of the data coordinating center for the multi-center, NICHD-funded Prophylaxis of Early Adrenal Insufficiency to Prevent Chronic Lung Disease in the Tiny Baby (PROPHET) study. Subsequently, I was PI of the NICHD-funded Statistical Methods for Clinical Trials with Twin Births project, evaluating statistical methodology relevant to clinical trials design and analysis. I have served as the primary statistician on three MRI-focused, NIH-funded studies. In addition, I have contributed to the statistical literature for modeling clinical studies in heterogeneous populations. My methodological and coordinating work complement my clinical trials and imaging experience, making me particularly suited to collaborate on the proposed work.

**B. Positions and Honors**

**Positions and Employment**

7/2002-6/2005 Assistant Professor, Department of Health Evaluation Sciences, Penn State College of Medicine, Hershey, PA

7/2005-6/2006 Assistant Professor, Department of Biostatistics, Boston University School of Public Health

7/2006-6/2008 Assistant Professor, Department of Public Health Sciences (previously called the Department of Health Evaluation Sciences), Division of Biostatistics, Joint Appointment in Department of Pediatrics, Penn State College of Medicine, Hershey, PA

7/2008-8/2012 Associate Professor, Department of Public Health Sciences, Division of Biostatistics and Bioinformatics, Joint Appointment in Department of Pediatrics, Penn State College of Medicine, Hershey, PA; Joint Appointment in Department of Statistics (beginning 2009), The Pennsylvania State University

9/2012-present Senior Staff Biostatistician, Center for Clinical and Translational Research; Associate Director, Children's Core for Biomedical Statistics, Seattle Children's Research Institute, Seattle, WA

**Other Experience and Professional Memberships**

1998-present Member, American Statistical Association

2001-present Member, International Biometric Society (ENAR)

2001-present Member, Institute of Mathematical Statistics

**Honors**

1995 Phi Beta Kappa

1997-1998 Penn State University Fellow

1998-1999 Homeyer Graduate Fellowship

2011 Dean's Award for Excellence in Teaching

**C. Selected Peer-reviewed Publications (from a total of 75)**

1. Watterberg KL, Gerdes JS, Cole CH, Aucott SW, Thilo EH, Mammel MC, Couser RJ, Garland JS, Rozycki HJ, Leach CL, Backstrom C, Shaffer ML. Prophylaxis of early adrenal insufficiency to prevent

- bronchopulmonary dysplasia: a multicenter trial. *Pediatrics* 2004; 114(6):1649-1657.
- Liu W, Zhao W, Shaffer ML, Icitovic N, Chase GA. Modelling clinical trials in heterogeneous samples. *Stat Med* 2005; 24(18):2765-2775.
  - Shaffer ML, Chinchilli VM. Including multiple imputation in a sensitivity analysis for clinical trials with treatment failures. *Contemp Clin Trials* 2007; 28(2):130-137.
  - Watterberg KL, Shaffer ML, Mishefske MJ, Leach CL, Mammel MC, Couser RJ, Abbasi S, Cole CH, Aucott SW, Thilo EH, Rozycki HJ, Lacy CB. Growth and neurodevelopmental outcomes after early low-dose hydrocortisone treatment in extremely low birth weight infants. *Pediatrics* 2007; 120(1):40-48.
  - Shaffer ML, Hiriotte S. Analysis of time-to-event and duration outcomes in neonatal clinical trials with twin births. *Contemp Clin Trials* 2009; 30(2):150-154.
  - Carroll JK, Lewis BA, Marcus BH, Lehman EB, Shaffer ML, Sciamanna CN. Computerized tailored physical activity reports: a randomized controlled trial. *Am J Prev Med* 2010; 39(2):148-156. PMID: PMC3140844
  - Du G, Lewis MM, Styner M, Shaffer ML, Sen S, Yang QX, Huang X. Combined R2\* and diffusion tensor imaging changes in the substantia nigra in Parkinson's disease. *Mov Disord* 2011; 26(9):1627-1632. PMID: PMC3154471
  - Wang J, Shaffer ML, Eslinger PJ, Sun X, Weitekamp CW, Patel MM, Dossick D, Gill DJ, Connor JR, Yang QX. Maturation and aging effects on human brain apparent transverse relaxation. *PLoS One* 2012; 7(2):e31907. PMID: PMC3283700
  - Du G, Lewis MM, Shaffer ML, Chen H, Yang QX, Mailman RB, Huang X. Serum cholesterol and nigrostriatal R2\* values in Parkinson's disease. *PLoS One* 2012; 7(4):e35397. PMID: PMC3328461
  - Du G, Lewis MM, Sen S, Wang J, Shaffer ML, Styner M, Yang QX, Huang X. Imaging nigral pathology and clinical progression in Parkinson's disease. *Mov Disord* 2012; in press.

#### **D. Research Support**

##### **Ongoing Research Support**

1 R01 AG032982 (Mitchell) 9/1/2009-8/31/2014

NIH (Subcontract to Hebrew Rehabilitation Center)

Determinants, Decision-making and Outcomes of Antibiotic Use in Advanced Dementia

The goal of this study is to assess antibiotic use in the advanced dementia population.

Role: Co-Investigator / PI of Subcontract

CFFRAMSEY03YO (Ramsey) 4/1/2003-3/31/2014

Cystic Fibrosis Foundation Therapeutics

Therapeutics Development Network Coordinating Center

The objectives of this coordinating center are to establish and manage a specialized network of research centers throughout the United States to perform clinical studies for the treatment of cystic fibrosis, and to provide the clinical, statistical, and data management infrastructure to support these studies.

Role: Biostatistician

UL1 RR 025014-02 (Disis) 6/1/2012-5/31/2017

NIH Cooperative Agreement

Institute for Translational Health Sciences- Children's Subcontract

To support space and infrastructure to provide support for clinical trial research at Seattle Children's Hospital.

This grant provides infrastructure support for Seattle Children's Research Institute Core for Biomedical Statistics, which provides an array of data management and biostatistical services for clinical studies, from the initial design stage to the final reporting phase, for researchers at Children's, the University of Washington and other local research institutes. Role: Associate Director, Seattle Children's Core for Biomedical Statistics

AquADEKs (Hamblett) 8/1/2012 - 7/31/2015

Cystic Fibrosis Foundation Therapeutics

Multicenter Study of the Effects of AquADEKs-2 on Markers of Inflammation and Oxidative Stress in CF

The purpose of this randomized, controlled (Phase II) study will be to further evaluate the effects of a modified formulation of AquADEKs® (AquADEKs-2) on antioxidant levels and markers of inflammation and oxidative stress. The results of this study will be used to determine whether to proceed with a larger Phase III trial targeting a clinical endpoint. Role: PhD Statistician

1 R01 AG043440 (Mitchell) 9/30/2012-8/31/2017

NIH (Subcontract to Hebrew Rehabilitation Center)

**EVINCE Educational Video to Improve Nursing Home Care in End-Stage Dementia**

The overall goal of the EVINCE study is to conduct a cluster randomized controlled trial of an advance care planning (ACP) video decision support tool among the proxies of nursing home residents with advanced dementia and examine the effect of the intervention of the stated goal of care, ACP, and burdensome treatments.

Role: Co-Investigator / PI of Subcontract

**Completed Research Support**

1 U49 CE01274 (Dias) 9/30/2007-8/31/2012

Centers for Disease Control (CDC)

PA Abusive Head Trauma Prevention Program

This study will assess the effectiveness of an established state-wide program of hospital-based postnatal parent education about violent infant shaking in reducing the incidence of abusive head trauma.

Role: Co-Investigator

1 UL1RR0330184 (Sinoway) 6/1/2011-8/31/2012

NIH

The Penn State Clinical and Translational Science Institute

The goal of Penn State CTSI is an engaged and responsive health science research and education enterprise that delivers on the promise of improved health. Role: Co-Leader, Biostatistics/Epidemiology/Research

Design Core

5 U01 HD054791 (Chinchilli) 9/28/2006-8/31/2012

NIH/NICHD

Data Coordination and Analyses Center for the Community & Child Health (CCHN) Network

The CCHN Data Coordination and Analyses Center provides biostatistical leadership, scientific coordination, data management, computer infrastructure, and data quality assurance for the CCHN Network.

Role: Co-Investigator

1 R01 ES019672 (Huang) 7/1/2011-8/31/2012

NIH/NIEHS

Regional Brain Manganese Accumulation and Functional Consequences in Welders

The proposed study will measure regional brain Mn deposition in response to environmental exposure, and delineate its functional correlations. Role: Co-Investigator

R01 NS060722 (Huang) 5/15/2009-8/31/2012

NIH

Structural MRI marker(s) of Parkinson's disease

The goal of this grant is to establish MRI measurements as widely available and reliable markers of Parkinson's disease (PD) progression. Role: Co-Investigator

1 R01 HL 097165 (Bixler-Liao) 5/1/2010-8/31/2012

NIH

Sleep and Cardio-Metabolic Risk Factors: a Prospective Study of Adolescents

The overall objective of this application is to assess a wide range of risk factors for, and subclinical and clinical consequences of early childhood obesity. Role: Co-Investigator

1R01NS067443-01A1 (Gerin) 9/1/2010-8/31/2012

NIH (Subcontract to Columbia University)

RCT: Effect of a Novel Intervention to Improve Stroke Symptom Recognition

This study is designed to educate children from families at elevated risk for stroke about symptoms and correct course of action in the event of a stroke, with the intent that the children will then educate their parents and grandparents. Role: Biostatistician

No Number Assigned (Singareddy) 2/1/2011-8/31/2012

Social Science Research Institute

Clinical and Neuroendocrine/Metabolic Benefits of Exercise in Treatment Resistant Depression (TRD): A Feasibility Study

This project will evaluate patients with TRD by performing standard fitness testing using maximal VO2 consumption protocol in patients with TRD who are sedentary at enrollment.

Role: Co-Investigator

No Number Assigned (Singareddy) 10/1/2011-8/31/2012

American Foundation for Suicide Prevention

Objective Sleep and Suicide in Youth

The goal of this project is to determine the association between serious suicidal ideations and objective/subjective sleep measures and the role of neurocognitive disturbances in mediating the effects of sleep disturbances on suicide in youth.

Role: Co-Investigator

1 R01 FD003410 (Thomas)

9/15/2009-12/31/2011

FDA Office of Orphan Products Development

A Phase III Trial of Calfactant for ALI in Pediatric Leukemia and HSCT Patients

This trial aims to replicate the benefits of calfactant therapy for pediatric leukemia/lymphoma patients and HSCT recipients.

Role: Co-Investigator

1 R01 AG027771 (Yang)

11/1/2007-10/31/2011

NIH/NIA

Neuroimaging Study on Function-Structure Relationship of Olfactory Deficit in Alzheimer's Disease

The long-term objective is to understand the olfactory deficits occurring in early AD and develop reliable diagnostic tools for early detection, monitoring and understanding the functional-pathological processes of AD.

Role: Co-Investigator

1 R01 ES014010 (Liao)

6/1/2008-10/30/2011

NIH/NIEHS

Air Pollution and Cardiac Risk: Mechanisms and Time-Course

The objective of this study is to investigate clinically relevant arrhythmogenic, cardiac autonomic control, repolarization, myocardial ischemia, blood pressure, inflammatory, coagulation, and fibrinolytic mechanisms and time course of PM2.5 effects.

Role: Co-Investigator

1 R01 HD052990 (Kjerulff)

4/1/2008-8/31/2010

NIH

Mode of First delivery and Subsequent Child-Bearing

The main goal of this project is to investigate the extent to which cesarean delivery increases a woman's risk of subsequent infertility.

Role: Co-Investigator

5 R01 AG024091 (Mitchell)

8/1/2006-7/31/2010

NIH (Subcontract to Hebrew Rehabilitation Center)

The Cascade Study: End of Life in Advanced Dementia

The purpose of this study is to follow nursing home residents with advanced dementia to assess physical comfort, decision-making, and satisfaction with end-of-life care.

Role: Co-Investigator / PI of Subcontract

1 R01 AG028423 (Mitchell)

9/1/2006-6/30/2010

NIH (Subcontract to Hebrew Rehabilitation Center)

The Adept Study: Estimating Prognosis in Advanced Dementia

The goal of the ADEPT study is to create a valid and practical risk score that will identify persons with advanced dementia at a high risk of death.

Role: Co-Investigator / PI of Subcontract

1 R40 MC06630 (Paul)

1/1/2006-12/31/2009

HRSA/MCHB

Single Home Visits to Improve Health Outcomes

The proposed research will prospectively evaluate the impact of a single home nursing visit on morbidities and health disparities for at-risk newborns and mothers in a randomized, controlled trial.

Role: Co-Investigator