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## EDUCATION

### **UNIVERSITY OF NORTH CAROLINA** (Chapel Hill, North Carolina)

Ph.D. in Biostatistics, December 1999

Supporting Program: Epidemiology

Dissertation: "Internal Pilot Study Design and Analysis for Linear Models with Gaussian Errors and Fixed Predictors," K. E. Muller, chair.

### **UNIVERSITY OF NORTH CAROLINA** (Chapel Hill, North Carolina)

M. S. in Biostatistics, December 1996

Master's Paper: "Exact Test Size and Power of a Gaussian Error Linear Model for an Internal Pilot Study," K. E. Muller, advisor.

### **UNIVERSITY OF TENNESSEE** (Knoxville, Tennessee)

B. S. in Business Administration, December 1992

Major: Statistics, Summa cum Laude

## ACADEMIC APPOINTMENTS

### **UNIVERSITY OF IOWA**

#### **DEPARTMENT OF BIostatISTICS (Iowa City, IA)**

2010-Present Director, Clinical Trials Statistical and Data Management Center (CTSDMC)

2009-Present Professor

2009-2010 Deputy Director, Clinical Trials Statistical and Data Management Center (CTSDMC)

### **UNIVERSITY OF ALABAMA AT BIRMINGHAM**

#### **DEPARTMENT OF BIostatISTICS (Birmingham, AL)**

2009-Present Adjunct Professor

2004-2009 Associate Professor

2001-2004 Assistant Professor

### **UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL**

#### **DEPARTMENT OF BIostatISTICS (Chapel Hill, NC)**

2005-2008 Adjunct Associate Professor

### **VANDERBILT UNIVERSITY MEDICAL CENTER**

#### **DIVISION OF BIostatISTICS (Nashville, TN)**

1999-2001 Assistant Professor

## TEACHING EXPERIENCE

### **UNIVERSITY OF IOWA**

#### **Advanced Clinical Trials (BIOS:7230)**

Doctoral Level – Elective Course

**Fall 2018:** Course Instructor

**Introduction to Translational Biomedicine (163:226)**

Institute for Clinical & Translational Sciences (ICTS) Course

**Fall 2018:** Presented lecture on “Phase II/III Clinical Trials”

**Spring 2017:** Presented lecture on “Phase II/III Clinical Trials”

**Fall 2015:** Presented lecture on “Phase II/III Designs”

**Fall 2014:** Presented lecture on “Phase I/II Designs”

**Iowa Summer Institute of Biostatistics**

**Summer 2010-2018:** Presented lecture on “Overview of Randomized Clinical Trials”

**Statistical Methods for Clinical Trials (BIOS:6610)**

Master’s Level – Elective Course

**Spring 2018:** Course Instructor

**Spring 2017:** Course Instructor

**Spring 2016:** Course Instructor

**Intervention and Clinical Trials (EPID:6900)**

Doctoral Level – Epidemiology Course

**Fall 2016-2017:** Presented lecture on “Adaptive Designs”

**Introduction to Translational Biomedicine (TBM:5001)**

Institute for Clinical & Translational Sciences (ICTS) Course

**Spring 2017:** Presented lecture on “Phase II/III Designs”

**Advanced Seminars in Clinical Trials (BIOS:7600 – ‘Advanced Clinical Trials’)**

Doctoral Level – Elective Course

**Fall 2016:** Course Instructor

**Comparative Effectiveness and Patient Centered Outcomes Research (BE-8025)**

Course Offered as Collaborative Effort among U. Iowa & U. Cincinnati CTSA

**Fall 2016:** Presented lecture on “Conventional & Emerging Methods in the Design of Clinical Trials”

**Intervention and Clinical Trials (173:290)**

Doctoral Level – Epidemiology Course

**Fall 2015:** Presented lecture on “Adaptive Designs”

**Fall 2011:** Presented lecture on “Adaptive Designs”

**Advanced Seminars in Clinical Trials (171:290 – ‘Advanced Clinical Trials’)**

Doctoral Level – Elective Course

**Fall 2014:** Course Instructor

**Fall 2013:** Course Instructor

**Fall 2011:** Course Instructor

**Spring 2010:** Course Instructor

**Applied Survival Analysis (171:242)**

Doctoral Level – Required Service Course / Elective Course

**Spring 2013:** Course Instructor

**Applied Cohort Analysis (171:243)**

Doctoral Level – Required Service Course / Elective Course

**Spring 2013:** Course Supervisor

**Applied Survival and Cohort Data Analysis (171:242)**

Doctoral Level – Required Service Course / Elective Course

**Spring 2011:** Course Instructor

## UNIVERSITY OF ALABAMA AT BIRMINGHAM

### Introduction to Survival Analysis (BST 665)

MS Level – Elective Course

**Spring 2009:** Course Instructor

**Spring 2007:** Course Instructor

**Spring 2005:** Course Instructor

**Spring 2003:** Course Instructor

**Summer 2001:** Co-Instructor (with Brent Shelton)

### Advanced Clinical Trials II (BST 726)

Doctoral Level – Elective Course

**Spring 2008:** Course Instructor

**Spring 2006:** Developed and Organized Course; Presented 7 lectures

### Advanced Clinical Trials I (BST 725)

Doctoral Level – Elective Course

**Fall 2007:** Presented three lectures – “DSMB Reports & Meetings”, “Interim Analysis”, & “Adaptive Designs”

**Fall 2005:** Presented four lectures on “Interim Analysis and Monitoring of Clinical Trials”

### Quantitative Methods (HMG 703)

Doctoral Level – Required Course

**Spring 2007:** Presented lecture on “Safety Monitoring”

### Theory of Linear Models (BST 723)

Doctoral Level – Required Course

**Fall 2005:** Course Instructor

**Fall 2003:** Course Instructor

**Summer 2002:** Course Instructor

### Applied Regression Analysis

MS Level – Applied Service Course

**Fall 2005:** Presented two lectures on “Choosing the Best Model”

**Fall 2004:** Presented two lectures on “Choosing the Best Model”

**Fall 2003:** Presented two lectures on “Choosing the Best Model”

**Fall 2002:** Presented two lectures on “Choosing the Best Model”

### Readings Course on ‘Internal Pilot Designs’ (BST 795)

Doctoral Level – Elective Readings Course

**Summer 2003:** Course Instructor

### Introduction to Data Management and Computing Using the SAS System (BST 626/627)

MS Level – Required Course

**Fall 2002:** Course Instructor

**Fall 2001:** Course Instructor

## VANDERBILT UNIVERSITY

**1999-2001:** Statistical consultant to Radiation Oncology Fellows Journal Club

### Fall 2000: Introductory Biostatistics.

Required introductory biostatistics course for first-year MPH students.

**Spring 2000:** Led Group Exercise on Case-Control/Cohort Studies for 2<sup>nd</sup> year medical students at Vanderbilt University School of Medicine

## UNIVERSITY OF NORTH CAROLINA

**1999:** Prepared and presented a lecture on "Power and Sample Size Calculations" for the course ‘Introduction to Statistical Consulting’.

**1997:** Teaching Assistant for 'Principles of Statistical Inference'  
(also presented a lecture on statistical power to the class)

## **SCHLEGEL, INC.**

**1993 - 1994:** Conducted Basic Statistics and Statistical Process Control training classes for all hourly employees and new hires at Hayward, CA and Keokuk, IA plants

## **UNIVERSITY OF TENNESSEE**

**1991-1992:** Teaching Assistant for 'Self Paced College Algebra' course

## **SHORT COURSES AND WORKSHOPS**

### *23. Medical Monitoring*

**October 2019:** Short Course at Annual Northeast ALS Consortium Meeting (Clearwater, FL)

**October 2018:** Short Course at Annual Northeast ALS Consortium Meeting (Clearwater, FL)

**October 2017:** Short Course at Annual Northeast ALS Consortium Meeting (Clearwater, FL)

### *22. Clinical Trials Methods in Neurology*

**July 2019:** Primary Faculty Member (Iowa City, IA)

**August 2018:** Primary Faculty Member (Ann Arbor, MI)

**August 2017:** Primary Faculty Member (Iowa City, IA)

**August 2016:** Primary Faculty Member (Ann Arbor, MI)

**July 2015:** Primary Faculty Member (Ann Arbor, MI)

**August 2014:** Primary Faculty Member (Iowa City, IA)

**August 2011:** Primary Faculty Member (Vail, CO)

**August 2010:** Primary Faculty Member (Vail, CO)

**August 2009:** Primary Faculty Member (Vail, CO)

**August 2008:** Primary Faculty Member (Vail, CO)

### *21. How to Design Meaningful Clinical Trials*

**May 2019:** Faculty Member, Short Course at American Academy of Neurology Annual Meeting (Philadelphia, PA)

### *20. Adaptive Designs – How Can We Achieve the Promise?*

**May 2018:** Pre-Conference Workshop, Society for Clinical Trials Annual Meeting (Portland, OR)

### *19. Clinical Trials in the Drug Development Pipeline*

**April 2018:** Faculty Member, Short Course at American Academy of Neurology Annual Meeting (Los Angeles, CA)

**April 2017:** Faculty Member, Short Course at American Academy of Neurology Annual Meeting (Boston, MA)

### *18. American Statistical Association Traveling Course – 'Adaptive Designs: Overview, Hurdles, & Examples'*

**April 2018:** Washington Statistical Society (Washington, DC)

**November 2017:** Trenton/Princeton Chapter (Piscataway, NJ)

**September 2017:** San Diego Chapter (San Diego, CA)

### *17. Adaptive Designs: Overview, Hurdles, Examples, & Software*

**May 2015:** Co-presenter with Daniele De Martini; Pre-Conference Workshop, Annual Meeting of the Society for Clinical Trials (Montreal, QC)

### *16. Adaptive Designs: Overview, Hurdles, & Examples*

**April 2015:** All Day Workshop, 8<sup>th</sup> Annual ADVAMed & American Statistical Association Statistical Issues Workshop (Washington, DC)

15. *Clinical Research: Drug Development and Clinical Trials*  
**April 2015:** Faculty Member, Short Course at American Academy of Neurology Annual Meeting (Washington, DC)
14. *Adaptive Designs*  
**January 2014:** Two-day short course sponsored by Rho, Inc. (Chapel Hill, NC)  
**September 2012:** Two-day short course sponsored by the University of Iowa CTSA (Iowa City, IA)
13. *Overview, Hurdles, and Future Work in Adaptive Designs*  
**September 2013:** Short Course offered at FDA/Industry Workshop (Washington, DC)
12. *Adaptive Designs and Small Clinical Trials*  
**November 2012:** Faculty Member; FDA-Sponsored Meeting the Challenges of Rare Disease Drug Review Short Course (Rockville, MD)
11. *Novel Designs for Rare Disorders, Including Adaptive Designs*  
**May 2012:** Faculty Member and Workshop Organizer; NIH-Sponsored Workshop on Designing Clinical Trials in Dystonia (Bethesda, MD)
10. *Challenges in Designing Small Clinical Trials*  
**May 2011:** Co-presenter with Janet Wittes; Pre-conference workshop held in conjunction with the Annual Meeting of the Society for Clinical Trials (Vancouver, BC)
9. *The Science of Small Clinical Trials*  
**April 2011:** Faculty Member (Silver Spring, MD)  
**February 2010:** Faculty Member (Silver Spring, MD)  
 Course, co-sponsored by the FDA Office of Orphan Products and NIH Office of Rare Diseases. (Bethesda, MD)
8. *Essentials of Randomized Clinical Trials*  
**May 2010:** Faculty member for pre-conference workshop at Annual Meeting of the Society for Clinical Trials (Baltimore, MD)
7. *Clinical Research Methods*  
**April 2010:** Faculty member for this short course held in conjunction with the Annual Meeting of the American Academy of Neurology (Toronto, ON)
6. *Scientific Advances in Adaptive Clinical Trial Design*  
**November 2009:** Co-organizer and presenter for two-day workshop (Bethesda, MD)
5. *Fundamentals of Randomized Clinical Trials*  
**May 2009:** Pre-conference workshop organized by myself and taught with Yves Rosenberg, Laura Lovato, Michele Melia, and Marta Marsh Gilson in conjunction with the annual meeting of the Society for Clinical Trials (Atlanta, GA)  
**May 2008:** Pre-conference workshop organized by myself and taught with Yves Rosenberg, Sylvan Green, Laura Lovato, Marta Marsh Gilson, and Michele Melia in conjunction with the annual meeting of the Society for Clinical Trials. (St. Louis, MO)
4. *Adaptive Dose-Response Studies*  
**August 2007:** Continuing Education Course taught with Brenda Gaydos and Jose Pinheiro in conjunction with the Annual Joint Statistical Meetings (Salt Lake City, UT)
3. *Frequentist Adaptive Designs, Internal Pilots, and Stopping Rules*  
**December 2006:** Lecture as part of a Conference on Design, Analysis, and Interpretation of Randomized Clinical Trials in Obesity (Newark, NJ)
2. *Adaptive Designs and Clinical Trials*  
**May 2005:** Pre-conference workshop taught with Cyrus Mehta in conjunction with the Annual Meeting of the Society for Clinical Trials (Portland, OR)

1. *Vanderbilt-Ingram Cancer Center Biostatistics Shared Resource Three Week Workshop*  
**March 2000:** Faculty Member

## WEBINARS

5. *Small Sample Size Clinical Trials*  
**May 2019:** Clinical Trials Methods in Neurology Course Webinar Series  
**July 2018:** Clinical Trials Methods in Neurology Course Webinar Series  
**May 2017:** Clinical Trials Methods in Neurology Course Webinar Series
4. *Increasing the Practicality of Innovative Trial Design*  
**March 2017:** Society for Clinical Trials Webinar Series
3. *Challenges in Designing Small Clinical Trials*  
**December 2011:** Sponsored by the Association for Research in Vision and Ophthalmology
2. *Adaptive Designs for Clinical Trials: Perspectives from an NIH-Funded Workshop*  
**May 2011:** Drug Information Association (DIA) Adaptive Design Working Group Key Opinion Leaders Lecture Series
1. *Adaptive Designs in Dose-Finding Studies*  
**November 2007:** Taught with Brenda Gaydos and Jose Pinheiro as part of a four-part web-based training series sponsored by PhRMA and the Biopharmaceutical section of the American Statistical Association.

## PUBLICATIONS AND PRESENTATIONS

### PEER REVIEWED PUBLICATIONS

150. Sorkin BC, Kuszak AJ, Fukagawa NK, Hoffman FA, Jafari M, Barrett B, Brown PN, Bushman FD, Casper S, Chilton FH, **Coffey CS**, Ferruzi MG, Hopp DC, Kiely M, Lakens D, MacMillan JB, Meltzer DO, Pahor M, Paul J, Pritchett-Cornign K, Quinney SK, Rehmann B, Setchell KDR, Sipes NS, Stephens JM, Taylor DL, Tiriach H, Walters WA, Xi D, Zappala G, and Pauli GF (2019). "Improving Natural Product Research Translation: From Source to Clinical Trial," *FASEB Journal*, in press.
149. Simuni T, Uribe L, Cho RH, Caspell-Garcia C, **Coffey CS**, Siderowf A, Trojanowski JQ, Shaw LM, Seibyl J, Singleton A, Toga AW, Galasko D, Foroud T, Tosun-Turgut D, Poston K, Poewe W, Weintraub D, Mollenhauer B, Tanner CM, Kieburtz K, Chahine LM, Reimer A, Hutten S, Bressman, and Marek K on behalf of the PPMI Investigators (2019). "Clinical and DAT Characteristics of Non-Manifest LRRK2 and GBA Mutation Carriers in the Parkinson's Progression Markers Initiative (PPMI): A Cross Sectional Study," *Lancet Neurology*, in press.
148. Chahine LM, Siderowf A, Barnes J, Seedorff N, Caspell-Garcia C, Simuni T, **Coffey CS**, Galasko D, Mollenhauer B, Arnedo V, Daegle N, Frasier M, Tanner C, Kieburtz K, Marek K and the Parkinson's Progression Markers Initiative (2019). "Predicting Progression in Parkinson's Disease Using Baseline and 1-Year Change Measures," *Journal of Parkinson's Disease*, 9(4): 665-679.
147. Paulsen JS and **Coffey CS** (2019). "Antisense Oligonucleotides Might Change the Therapeutic Landscape for Huntington's Disease," *Lancet Neurology*, 18(10): 911-912.
146. Mollenhauer B, Caspell-Garcia CJ, **Coffey CS**, Taylor P, Singleton A, Shaw LM, Trojanowski JQ, Frasier M, Simuni T, Iranzo A, Oertel W, Siderowf A, Weintraub D, Seibyl J, Toga AW, Tanner CM, Kieburtz K, Chahine LM, Marek K, and Galasko D for the PPMI Study (2019). "Longitudinal Analyses of Cerebrospinal Fluid  $\alpha$ -Synuclein in Prodromal and Early Parkinson's Disease," *Movement Disorders*, 34(9): 1354-1364.

145. Prakash N, Caspell-Garcia C, **Coffey C**, Siderowf A, Tanner CM, Kieburtz K, Mollenhauer B, Galasko D, Merchant K, Foroud T, Chahine LM, Weintraub D, Casaceli C, Dorsey R, Wilson R, Herzog M, Daegele N, Arnedo V, Frasier M, Sherer T, Marek K, & Simuni T on behalf of the Parkinson's Progression Markers Initiative Steering Committee, Study Cores, Site Investigators, Coordinators, and Industry & Scientific Advisory Board (2019). "Feasibility and Safety of Lumbar Puncture in the Parkinson's Disease Research Participants: Parkinson's Progression Marker Initiative (PPMI)", *Parkinsonism & Related Disorders*, 62: 201-209.
144. Espay AJ, Foster ED, **Coffey CS**, Uribe L, Caspell-Garcia CJ, Weintraub D, and the Parkinson's Progression Markers Initiative (2019). "Lack of Independent Mood-Enhancing Effect for Dopaminergic Medications in Early Parkinson's Disease," *Journal of the Neurological Sciences*, 402: 81-85.
143. Amara AW, Chahine L, Seedorff N, Caspell-Garcia CJ, **Coffey C**, Simuni T, and the Parkinson's Progression Markers Initiative (2019). "Self-Reported Physical Activity Levels and Clinical Progression in Early Parkinson's Disease," *Parkinsonism & Related Disorders*, 61: 118-125.
142. Lyden P, Pryor KE, **Coffey CS**, Cudkowicz M, Conwit R, Jadhav A, Sawyer Jr RN, Claassen J, Adeoye O, Song S, Hannon P, Rost NS, Hinduja A, Torbey M, Lee J, Benesch C, Rippee M, Rymer M, Froehler MT, Haley EC, Johnson M, Yankey J, and Magee K (2019). "Final Results of the RHAPSODY Trial: A Multi-Center, Phase 2 Trial Using A Continual Reassessment Method to Determine the Safety and Tolerability of 3K3A-APC, A Recombinant Variant of Human Activated Protein C, In Combination with Tissue Plasminogen Activator, Mechanical Thrombectomy or Both in Moderate to Severe Acute Ischemic Stroke," *Annals of Neurology*, 85(1): 125-136.
141. Chahine LM, Beach TG, Seedorff N, Caspell-Garcia C, **Coffey CS**, Brumm M, Adler CH, Serrano GE, Linder C, Mosovsky S, Foroud T, Riss H, Ecklund D, Seibyl J, Jennings D, Arnedo V, Riley L, Dave K, and Mollenhauer B on behalf of the Systemic Synuclein Sampling Study (2018). "Feasibility and Safety of Multicenter Tissue and Biofluid Sampling for  $\alpha$ -Synuclein in Parkinson's Disease: The Systemic Synuclein Sampling Study (S4)," *Journal of Parkinson's Disease*, 8(4): 517-527.
140. Krosschell KJ, Bosch M, Nelson L, Duong T, Lowes LP, Alfano LN, Benjamin D, Carry TB, Devine G, Kelley C, Gadekan R, Malkus EC, Pasternak A, Provance-Orr S, Roemeiser-Logan L, Nicorici A, Trussell D, Young SD, Fetterman JR, Montes J, Powers PJ, Quinones R, Quigley J, **Coffey CS**, Yankey JW, Bartlett A, Kissell JT, Kolb SJ, and the NeuroNEXT Clinical Trial Network on behalf of the NN101 SMA Biomarker Investigators (2018). "Motor Function Test Reliability During the NeuroNEXT Spinal Muscular Atrophy Infant Biomarker Study," *Journal of Neuromuscular Diseases*, 5(4): 509-521.
139. Marek K, Chowdhury S, Siderowf A, Lasch S, **Coffey CS**, Caspell-Garcia C, Simuni T, Jennings D, Tanner CM, Trojanowski JQ, Shaw LM, Seibyl J, Schuff N, Singleton A, Kieburtz K, Toga AW, Mollenhauer B, Galasko D, Chahine LM, Weintraub D, Foroud T, Tosun-Turgut D, Poston K, Arnedo V, Frasier M, Sherer T, and the Parkinson's Progression Markers Initiative (2018). "The Parkinson's Progression Markers Initiative (PPMI) – Establishing a PD Biomarker Cohort," *Annals of Clinical and Translational Neurology*, 5(12): 1460-1477.
138. Fox RJ, **Coffey CS**, Conwit R, Cudkowicz ME, Gleason T, Goodman A, Klawiter EC, Matsuda K, McGovern M, Naismith RT, Ashokkumar A, Barnes J, Ecklund D, Klingner E, Koeppe M, Long JD, Natarajan S, Thornell B, Yankey J, Bermel RA, Debbins JP, Huang X, Jagodnik P, Lowe MJ, Nakamura K, Narayanan S, Sakaie KE, Thoomukuntla B, Zhou X, Krieger S, Alvarez E, Apperson M, Bashir K, Cohen BA, Coyle PK, Delgado S, Dewitt LD, Flores A, Giesser BS, Goldman MD, Jubelt B, Lava N, Lynch SG, Moses H, Ontaneda D, Perumal JS, Racke M, Repovic P, Riley CS, Severson C, Shinnar S, Suski V, Weinstock-Guttman B, Yadav V, and Zabeti A on behalf of the NN102/SPRINT-MS Trial Investigators (2018). "Phase 2 Trial of Ibudilast in Progressive Multiple Sclerosis," *New England Journal of Medicine*, 379(9): 846-855.

137. Chahine LM, Uribe L, Caspell-Garcia C, Aarsland D, Alcalay R, Barone P, Burn D, Espay AJ, Hamilton JL, Hawkins KA, Lasch S, Leverenz JB, Litvan I, Richard I, Siderowf A, **Coffey CS**, Simuni T, Weintraub D, and the Parkinson's Progression Markers Initiative (2018). "Cognition Among Individuals Along a Spectrum of Increased Risk for Parkinson's Disease," *PLOS ONE*, 13(8): e0201964.
136. Beach TG, Serrano G, Kremer T, Canamero M, Dziadek S, Sade H, Derkinderen P, Corbille AG, Letournel F, Munoz DG, White CL, Schneider J, Crary JF, Sue LI, Adler CH, Glass MJ, Intorcchia AJ, Walker JE, Foroud T, **Coffey CS**, Ecklund D, Riss H, Goldmann J, Konig F, Kopil CM, Arnedo V, Riley L, Linder C, Dave KD, Jennings D, Seibyl J, Mollenhauer B, and Chahine L on behalf of the Systemic Synuclein Sampling Study (2018). "Immunohistochemical Method and Histopathology Judging for the Systemic Synuclein Sampling Study (S4)," *Journal of Neuropathology and Experimental Neurology*, 77(9): 793-802.
135. Bartlett A, Kolb SJ, Kingsley A, Swoboda KJ, Reyna SP, Sakonju A, Darras BT, Shell R, Kuntz N, Castro D, Iannaccone ST, Parsons J, Connolly AM, Chiriboga A, McDonald C, Burnette B, Werner K, Thangarajh M, Shieh PB, Finanger E, **Coffey CS**, Yankey JW, Cudkovicz ME, McGovern MM, McNeil E, Arnold WD, and Kissel JT for the NeuroNEXT Clinical Trial Network and on behalf of the NN101 SMA Biomarker Investigators (2018). "Recruitment & Retention Program for the NeuroNEXT SMA Biomarker Study: Super Babies for SMA!" *Contemporary Clinical Trials Communications*, 11: 113-119.
134. Simuni T, Siderowf A, Lasch S, **Coffey CS**, Caspell-Garcia C, Jennings D, Tanner CM, Trojanowski JQ, Shaw LM, Seibyl J, Schuff N, Singleton A, Kiebertz K, Toga AW, Mollenhauer B, Galasko D, Chahine LM, Weintraub D, Foroud T, Tosun D, Poston K, Arnedo V, Frasier M, Sherer T, Chowdhury S, and Marek K on behalf of the PPMI Investigators (2018). "Longitudinal Change of Clinical and Biological Measures in Early Parkinson's Disease: Parkinson's Progression Markers Initiative Cohort," *Movement Disorders*, 33(5): 771-782.
133. Anderegg MD, Gums TH, Uribe L, MacLaughlin EJ, Hoehns J, Bazaldua OV, Ives TJ, Hahn DL, **Coffey CS**, and Carter BL (2018). "Pharmacist Intervention for Blood Pressure in Patients with Diabetes and/or Chronic Kidney Disease," *Pharmacotherapy*, 38(3): 309-318.
132. Simuni T, Caspell-Garcia C, Walker M, **Coffey C**, Weintraub D, Mollenhauer B, Lasch S, Tanner C, Jennings D, Kiebertz K, Chahine L, and Marek K on behalf of the PPMI Investigators (2018). "Baseline Prevalence and Longitudinal Evolution of Non-Motor Symptoms in Early Parkinson's Disease: The PPMI Cohort," *Journal of Neurology, Neurosurgery, & Psychiatry*, 89(1): 78-88.
131. Kolb SJ, **Coffey CS**, Yankey JW, Krosschell KP, Arnold WD, Rutkove SB, Swoboda KJ, Reyna SP, Sakonju A, Darras BT, Shell R, Kuntz N, Castro D, Parsons J, Connolly A, Chiriboga CA, McDonald C, Burnette B, Werner W, Thangarajh M, Shieh P, Finanger E, Cudkovicz M, McGovern MM, McNeil DE, Finkel R, Iannaccone ST, Kaye E, Kingsley A, Renusch SR, McGovern VL, Wang X, Zaworski PG, Prior TW, Burghes A, Bartlett AHM, Kissel JT and The NeuroNEXT Clinical Trial Network on behalf of the NN101 SMA Biomarker Investigators (2017). "Natural History of Infantile-Onset Spinal Muscular Atrophy," *Annals of Neurology*, 82(6): 883-891.
130. Mollenhauer B, Caspell-Garcia CJ, **Coffey CS**, Taylor P, Shaw LM, Trojanowski JQ, Singleton A, Frasier M, Marek K, and Galasko D for the PPMI Study (2017). "Longitudinal CSF Biomarkers in Early Parkinson's Disease and Healthy Controls," *Neurology*, 89(19): 1959-1969.
129. Amara AW, Chahine LM, Caspell-Garcia C, Long JD, **Coffey C**, Hogg B, Videnovic A, Iranzo A, Mayer G, Foldvary-Schaefer N, Postuma R, Oertel W, Lasch S, Marek K, Simuni T, and the Parkinson's Progression Markers Initiative (2017). "Longitudinal Assessment of Excessive Daytime Sleepiness in Early Parkinson's Disease," *Journal of Neurology, Neurosurgery, & Psychiatry*, 88: 653-662.



128. Mollenhauer B, Batrla R, El-Agnaf O, Galasko DR, Lashuel HA, Merchant KM, Shaw LM, Selkoe DJ, Umek R, Vanderstichele H, Zetterberg H, Zhang J, Caspell-Garcia C, **Coffey C**, Hutten SJ, Frasier M, and Taylor P for the Investigating Synuclein Consortium of the Michael J. Fox Foundation for Parkinson's Research (2017). "A User's Guide for  $\alpha$ -Synuclein Biomarker Studies in Biological Fluids: Peri-Analytical Considerations," *Movement Disorders*, 32(8): 1117-1130.
127. Caspell-Garcia C, Simuni T, Tosun-Turgut D, Wu I, Zhang Y, Nalls M, Singleton A, Shaw LA, Kang JH, Trojanowski JQ, Siderowf A, **Coffey C**, Lasch S, Aarsland D, Burn D, Chahine LM, Espay AJ, Foster ED, Hawkins KA, Litvan I, Richard I, and Weintraub D on behalf of the Parkinson's Progression Markers Initiative (PPMI) (2017). "Multiple Modality Biomarker Prediction of Cognitive Impairment in Prospectively Followed De Novo Parkinson's Disease," *PLoS ONE*, 12(5): e0175674.
126. Powers SW, **Coffey CS**, and Hershey AD (2017). "Treatment of Pediatric Migraine," *The New England Journal of Medicine*, 376(14): 1388-1389.
125. Pont-Sunyer C, Tolosa E, Caspell-Garcia C, **Coffey C**, Alcalay RN, Chans P, Duda JE, Facheris M, Fernandez-Santiago R, Marek K, Lomena F, Marras C, Mondragon E, Saunders-Pullman R, and Waro B on behalf of the LRRK2 Cohort Consortium (2017). "The Prodromal Phase of LRRK2 Associated Parkinson Disease: Clinical and Imaging Studies," *Movement Disorders*, 32(5): 726-738.
124. Visanji NP, Mollenhauer B, Beach TG, Adler CH, **Coffey CS**, Kopil CM, Dave KD, Foroud T, Chahine L, and Jennings D on behalf of the Systemic Synuclein Sampling Study (S4) Investigators (2017). "The Systemic Synuclein Sampling Study: Toward a Biomarker for Parkinson's Disease," *Biomarkers in Medicine*, 11(4): 359-368.
123. Powers SW, Hershey AD, and **Coffey CS** on behalf of the CHAMP Study Group (2017). "The Childhood and Adolescent Migraine Prevention (CHAMP) Study: 'What Do We Do Now?'," *Headache*, 57(2): 180-183.
122. Powers SW, **Coffey CS**, Chamberlin LA, Ecklund DJ, Klingner EA, Yankey JW, Korbee LL, Porter LL, & Hershey AD for the CHAMP Investigators (2017). "Trial of Amitriptyline, Topiramate, and Placebo for Pediatric Migraine," *The New England Journal of Medicine*, 376(2): 115-124.
121. Laage T, Loewy J, Menon S, Miller E, Pulkstenis E, Kan-Dobrosky N, & **Coffey C** (2016). "Ethical Considerations in Novel Adaptive Design Clinical Trials," *Therapeutic Innovation & Regulatory Science*, 51(2): 190-199.
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30. **Coffey CS**, Hebert PR, Krumholz HM, Morgan TM, Williams SM, and Moore JH. (2004) "Reporting of Model Validation Procedures in Human Studies of Genetic Interactions," *Nutrition*, **20**: 69-73.
29. Neuzil KM, **Coffey CS**, Mitchel EF, and Griffin MR. (2003) "Cardiopulmonary Hospitalizations During Influenza Season in Adults and Adolescents with Advanced HIV Infection," *Journal of Acquired Immune Deficiency Syndromes*, **34**: 304-307.
28. Gadbury GL, **Coffey CS**, and Allison DB. (2003) "Modern Statistical Methods for Handling Missing Repeated Measurements in Obesity Trial Data: Beyond LOCF," *Obesity Reviews*, **4**: 175-184.
27. **Coffey CS** and Muller KE. (2003) "Properties of Internal Pilots with the Univariate Approach to Repeated Measures," *Statistics in Medicine*, **22**: 2469-2485.
26. Morgan TM, **Coffey CS**, and Krumholz HM. (2003) "Overestimation of Gene-Associated Risks Due to Small Sample Size in Cardiovascular Genetic Case-Control Studies," *Clinical Genetics*, **64**: 7-17.
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18. Dutta SC, Chang SC, **Coffey CS**, Smith JA Jr, Jack G, and Cookson MS. (2002) "Health Related Quality of Life Assessment after Radical Cystectomy: Comparison of Ileal Conduit with Continent Orthotopic Neobladder," *Journal of Urology*, **168(1)**: 164-167.



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16. Allison DB and **Coffey CS**. (2002) "Two-Stage Testing in Microarray Analysis: What is Gained?," *Journal of Gerontology: Biological Sciences*, **57**: B189-B192.
15. Grossklaus DJ, **Coffey CS**, Shappell SB, Jack GS, Chang SS, and Cookson MS. (2002) "Percent of Cancer in the Biopsy Set Correlates with Pathologic Findings after Prostatectomy," *Journal of Urology*, **167(5)**, 2032-2036.
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11. Dutta SC, Smith JA, Shappell SB, **Coffey CS**, Chang SS, and Cookson MS. (2001) "Clinical Understaging of High Risk Nonmuscle Invasive Urothelial Carcinoma Treated with Radical Cystectomy," *Journal of Urology*, **166**, 490-493.
10. **Coffey CS** and Muller KE. (2001) "Controlling Test Size While Gaining the Benefits on an Internal Pilot Design," *Biometrics*, **57**, 625-631.
9. Cardin S, Jackson PA, Edgerton DS, Neal DW, **Coffey CS**, and Cherrington AD. (2001) "Effect of Vagal Cooling on the Counterregulatory Response to Hypoglycemia Induced by a Low Dose of Insulin in the Conscious Dog," *Diabetes*, **50**, 558-564.
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7. **Coffey CS** and Muller KE. (2000) "Some Distributions and Their Implications for an Internal Pilot Study with a Univariate Linear Model," *Communications in Statistics-Theory and Methods*, **29(12)**, 2677-2691.
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5. **Coffey CS** and Muller KE. (2000) "Properties of Doubly-Truncated Gamma Variables," *Communications in Statistics-Theory and Methods*, **29(4)**, 851-857.
4. Hemminger BM, Dillon A, Johnston RE, Muller KE, Pisano E, Deluca M, and **Coffey C**. (1999) "Effect of Display Luminance on the Feature Detection Rates of Masses in Mammograms," *Medical Physics*, **26(11)**, 2266-2272.
3. **Coffey CS** and Muller KE. (1999) "Exact Test Size and Power of a Gaussian Error Linear Model for an Internal Pilot Study," *Statistics in Medicine*, **18**, 1199-1214.
2. Bullitt E, Liu A, Aylward S, **Coffey C**, Stone J, Mukherji SK, Muller K, and Pizer SM. (1999) "Registration of 3D Cerebral Vessels with 2D Digital Angiograms: Clinical Evaluation," *Academic Radiology*, **6**, 539-546.

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### INVITED BOOK CHAPTERS

2. **Coffey CS**. "Adaptive Design across Stages of Development." *Clinical Trials in Neurology*. Eds: Ravina B, Cummings MP, McDermott MP, and Poole M. Cambridge University Press, 2012, 91-100.
1. **Coffey CS** and Cofield SS. "Parametric Linear Models." *DNA Microarrays and Related Genomic Techniques: Design, Analysis, and Interpretation of Experiments*. Eds: Allison DB, Page GP, Beasley TM, and Edwards JW. Boca Raton: Chapman & Hall/CRC, 2005, 223-243.

### OTHER PUBLICATIONS

7. Hoffman EP on behalf of **Workshop Participants** and the TREAT-NMD Alliance (2017). "Facilitating Orphan Drug Development: Proceedings of the TREAT-NMD International Conference, December 2015, Washington, DC, USA," *Neuromuscular Disorders*, 27(7): 693-701.
6. **Coffey CS** (2010). "Power Analysis," In *Encyclopedia of Research Design*, NJ Salkind (ed.), Publisher: Sage, Thousand Oaks, CA.
5. Kairalla JA, **Coffey CS**, and Muller KE (2010). "Achieving the Benefits of Both an Internal Pilot and Interim Analysis in Small Samples," *2010 Proceedings of the Joint Statistical Meetings*, ENAR Section, 5239-5252.
4. Ritchie MD, **Coffey CS**, and Moore JH. (2005) "Genetic Programming Neural Networks as a Bioinformatics Tool for Human Genetics," *Lecture Notes in Computer Science: Genetic and Evolutionary Computation – GECCO 2004 Conference Proceedings*, **3102**: 438-448.
3. **Coffey CS** and Muller KE. (2003) "Practical Methods for Bounding Test Size with an Internal Pilot Design," *2003 Proceedings of the Joint Statistical Meetings*, Biopharmaceutical Section [CD-ROM].
2. **Coffey CS** and Muller KE. (2001) "GLUMIP 1.0: Free SAS IML Software for Internal Pilots," *2001 Proceedings of the Joint Statistical Meetings*, Biometrics Section [CD-ROM].
1. Bullitt E, Aylward S, Liu A, Stone J, Mukherji S, **Coffey C**, Gerig G, and Pizer SM. (1999) "3D Graph Description of the Intracerebral Vasculature from Segmented MRA and Tests of Accuracy by Comparison with X-Ray Angiograms," *Lecture Notes in Computer Science*, **1613**, 308-321.

### INVITED PRESENTATIONS

62. *The Clinical Trials Statistical & Data Management Center (CTSDMC) – History & Current Neurological Activities*  
**July 2019**: University of Iowa Department of Neurology Grant Rounds (Iowa City, IA)
61. *An Overview of Data Sharing*  
**May 2019**: Society for Clinical Trials Annual Meeting (New Orleans, LA); Part of an Invited Session on "Preparing and Submitting Data to Open and Limited-Access Repositories" (Organizer: Janel Fedler, University of Iowa)
60. *An Overview of NeuroNEXT*  
**May 2019**: Society for Clinical Trials Annual Meeting (New Orleans, LA); Part of an Invited Session on "Switching Boats Mid-Stream: Maintaining Continuity in a Large Clinical Trials Network in the Face of Change" (Organizer: Julie Qidwai, University of Iowa)
59. *Novel Trial Designs of 'Disease Modifying Therapy' in Oncology (e.g., I-SPY2) and Other Diseases*  
**April 2019**: The Krembil Knowledge Gaps in Parkinson's Disease Symposium (Toronto, Canada)
58. *Achieving the Promise of Innovative Clinical Designs in an Academic Setting*  
**January 2019**: Duke University (Durham, NC)  
**August 2018**: University of Minnesota (Minneapolis, MN)

57. *Innovative Statistical Design and Analysis in ALS*  
**November 2018:** Massachusetts ALS Partnership Symposium (Boston, MA)  
**October 2018:** 17<sup>th</sup> Annual Northeast ALS Consortium Annual Meeting (Clearwater, FL)
56. *Design Considerations When Planning Clinical Trials*  
**September 2018:** “Enhancing Natural Products Clinical Trials” Workshop (Bethesda, MD)
55. *We Built This Network: How NeuroNEXT Increases Innovative Design in Academic Trials*  
**August 2018:** University of Iowa College of Public Health Distinguished Faculty Lecture (Iowa City, IA)
54. *What We Measure and How: Outcomes Panel*  
**July 2018:** ALS Community Workshop – Therapy Development & Regulatory Discussion; Panel Discussion w/ Drs. Jeremy Shefner (Barrow Neurological Institute), Steve Hersch (Voyager Therapeutics), and Madeline Kennedy (Person w/ ALS; Washington, DC)
53. *Adaptive Timing of Interim Analysis: DSMB Perspective*  
**May 2018:** Society for Clinical Trials Annual Meeting (Portland, OR)
52. *University of Iowa Clinical Trials Statistical & Data Management Center – Overview of Ongoing Parkinson’s Disease Research Efforts*  
**April 2018:** University of Iowa Site Visit for Parkinson’s Foundation Center of Excellence Evaluation (Iowa City, IA)
51. *University of Iowa Clinical Trials Statistical & Data Management Center – Overview of Ongoing Collaborations with the Michael J. Fox Foundation*  
**April 2018:** Eastern Iowa Parkinson’s Symposium (Cedar Rapids, IA)
50. *Innovative Statistical Design and Analysis in PD*  
**February 2018:** The International Society for CNS Clinical Trials & Methodology Annual Meeting (Washington, DC)
49. *Utilizing NIH Networks for Clinical Trials: Lessons from the Trenches*  
**July 2017:** Cleveland Clinic (Cleveland, OH – Co-Presenter w/ Merit Cudkowicz, MGH; Robin Conwit, NINDS; Codrin Lungu, NINDS)
48. *Implementing Adaptive Designs: Balancing the Practical with the Statistical*  
**May 2017:** Discussant, Society for Clinical Trials Annual Meeting (Liverpool, UK)
47. *Statistical Aspects of the Childhood & Adolescent Migraine Prevention (CHAMP) Study*  
**April 2017:** UAB Department of Biostatistics (Birmingham, AL)
46. *Increasing the Practicality of Innovative Trial Designs*  
**April 2017:** DIA Adaptive Design Scientific Working Group Key Opinion Leaders Webinar Series  
**March 2017:** The Society for Clinical Trials Webinar Series  
**March 2017:** Iowa Department of Biostatistics Seminar Series (Iowa City, IA)  
**December 2016:** National Institute of Neurological Disorders & Stroke (Bethesda, MD)  
**April 2016:** University of Florida Department of Biostatistics (Gainesville, FL)  
**October 2015:** UAB Department of Biostatistics (Birmingham, AL)  
**April 2015:** Keynote Address at 8<sup>th</sup> Annual ADVAMed & American Statistical Association Statistics Workshop (Washington, DC)
45. *Challenges and Experience in Designing Small Clinical Trials*  
**August 2016:** Invited Session at Joint Statistical Meetings (Chicago, IL)
45. *NeuroNEXT Overview & Accomplishments*  
**July 2016:** The Ohio State University School of Medicine (Columbus, OH)

44. *Adaptive & Bayesian Trial Design*  
**February 2016:** ICTS Sponsored Workshop on Patient-Centered Outcomes and Comparative Effectiveness Research (Cincinnati, OH)
43. *The State of the Clinical Trials Statistical and Data Management Center*  
**February 2016:** Iowa Department of Biostatistics Seminar Series (Iowa City, IA)
42. *Innovative Trial Designs for Rare Disease*  
**December 2015:** TREAT-NMD International Conference (Washington, DC)
41. *Common Data Elements: The User's Perspective*  
**May 2015:** Invited Session at Annual Society for Clinical Trials Meeting (Washington, DC)
40. *Overview of the Clinical Trials Statistical and Data Management Center & NeuroNEXT*  
**April 2015:** Iowa Department of Epidemiology Seminar Series (Iowa City, IA)
39. *Re-Estimating Sample Size Midtrial: The SPS3 Experience*  
**April 2015:** 8<sup>th</sup> Annual ADVAMed & American Statistical Association Statistics Workshop (Washington, DC)
38. *Small Phase II Trials*  
**March 2015:** ALS Association Patient Webinar Series
37. *Overview, Hurdles, and Future Work in Adaptive Designs*  
**August 2014:** American Statistical Association Webinar Series
36. *Adaptive Trial Designs*  
**February 2014:** Alpha-One Foundation Sponsored Workshop on 'Clinical Trial Design for Alpha-1 Antitrypsin Deficiency: A Model for Rare Diseases' (Bethesda, MD)
35. *Challenges in Designing Clinical Trials for Rare Diseases*  
**September 2013:** FDA/Industry Workshop (Washington, DC)
34. *Overview of Adaptive Designs, and Extensions beyond Clinical Trials*  
**July 2013:** East Tennessee State University College of Public Health (Johnson City, TN)
33. *Revolutionizing Clinical Trials by Creating Infrastructure for Phase 2 Trials in Neurological Disorders*  
**May 2013:** Invited Session at Annual Society for Clinical Trials Meeting (Panel with Cudkowicz M, Kearney M, Ecklund D, McNeil E; Boston, MA)
32. *An Overview of Adaptive Designs*  
**March 2013:** College of Nursing Seminar Series, University of Iowa (Iowa City, IA)
31. *Overview, Hurdles, and Future Work in Adaptive Designs*  
**February 2013:** Department of Statistics, University of Iowa (Iowa City, IA)  
**May 2011:** Mackey Cancer Center, University of Kentucky (Lexington, KY)
30. *Overview of Randomized Clinical Trials*  
**September 2012:** Department of Obstetrics/Gynecology Seminar Series, University of Iowa (Iowa City, IA)
29. *Quantitative Pitfalls in Comparative Effectiveness Research and How to Avoid Them*  
**February 2012:** Department of Internal Medicine Grand Rounds, University of Florida (with KE Muller & RI Shorr; Gainesville, FL)
28. *Building a Clinical Studies Database*  
**December 2011:** NINDS Sponsored Parkinson's Disease Biomarkers Resource Data Management Workshop (Bethesda, MD)
27. *Use of Adaptive Designs in Clinical Effectiveness Trials*  
**November 2011:** University of Iowa CTSA Lecture Series (Iowa City, IA)

26. *Adaptive Designs and Small Clinical Trials*  
**October 2011:** FDA/Industry Workshop (Washington, DC)  
**October 2011:** US Conference on Rare Diseases and Orphan Products (Washington, DC)  
**March 2011:** US FDA Center for Biologics Evaluation and Research (Rockville, MD)  
**March 2011:** US FDA Center for Drug Evaluation and Research Office of Biostatistics (Silver Spring, MD)
25. *Adaptive Design for Clinical Trials: Perspectives from an NIH-Funded Workshop*  
**May 2011:** Drug Information Association (DIA) Adaptive Design Working Group KOL Lecture Series (webinar)
24. *Hurdles and Future Work in Adaptive Designs*  
**April 2011:** University of Pennsylvania Clinical Trials Symposium (Philadelphia, PA)
23. *Biostatistics*  
**October 2010:** Fourth Annual Iowa Mathematical Field of Dreams Conference (Iowa City, IA)
22. *Adaptive Designs*  
**November 2009:** Huntington Disease Study Group (Baltimore, MD)
21. *The Emerging Role of the Data and Safety Monitoring Board: Implications of Adaptive Clinical Trial Designs*  
**Oct 2009:** University of Rochester (Rochester, NY)  
**June 2009:** Annual Meeting of the Southern Research Council on Statistics (Jekyll Island, GA)
20. *Avoiding the Pitfalls of a Meta-Analysis*  
**April 2009:** Third Annual Methods in Epidemiology and Outcomes Research Symposia, University of Alabama at Birmingham (Birmingham, AL)
19. *Internal Pilot Designs: They're Not Just for Clinical Trials Anymore*  
**December 2008:** Department of Biostatistics, The University of Iowa (Iowa City, IA)
18. *Internal Pilot Designs: An Overview and Recent Extensions*  
**November 2008:** Department of Public Health Sciences, University of Virginia (Charlottesville, VA)  
**October 2008:** College of Public Health, The Ohio State University (Columbus, OH)
17. *Internal Pilot Designs for Cluster Samples*  
**August 2008:** Joint Statistical Meetings (Denver, CO)
16. *Advantages and Disadvantages When Implementing an Adaptive Design in an NIH-Funded Study*  
**August 2007:** Joint Statistical Meetings (Salt Lake City, UT)
15. *Treatment Effect in Sample Size Determination: Clinical vs. Statistical Significance*  
**May 2007:** Annual Meeting of the Society for Clinical Trials (Montreal, Quebec, Canada)
14. *Activities of the Statistical Center for the Secondary Prevention of Small Subcortical Strokes (SPS3) Trial*  
**May 2007:** Clinical Trials and Data Management Center, Department of Biostatistics, University of Iowa (Iowa City, IA)
13. *Clarifying the Controversy Surrounding Adaptive Designs for Sample Size Re-Estimation*  
**May 2007:** Department of Biostatistics, University of Iowa (Iowa City, IA)  
**March 2007:** Department of Epidemiology and Health Policy Research, University of Florida (Gainesville, FL)
12. *An Introductory Overview Lecture on Adaptive Designs/Internal Pilots*  
**August 2006:** Annual Joint Statistical Meetings (Seattle, WA)

11. *Adaptive and Internal Pilot Designs*  
**December 2006:** Department of Neurology, Columbia University Medical Center (New York, NY)  
**June 2006:** Department of Epidemiology and Health Policy Research, University of Florida (Gainesville, FL)  
**April 2006:** Department of Public Health, East Tennessee State University (Johnson City, TN)
10. *Internal Pilot Designs for Medical Imaging Studies*  
**March 2006:** Department of Biostatistics, University of North Carolina at Chapel Hill (Chapel Hill, NC)
9. *An Overview of Adaptive Designs with Emphasis on Internal Pilots*  
**March 2006:** Health Services Administration Doctoral Seminar, University of Alabama at Birmingham (Birmingham, AL)  
**November 2005:** Medical Statistics Section Seminar Series, University of Alabama at Birmingham Comprehensive Cancer Center (Birmingham, AL)  
**October 2005:** Center for Nursing Research Seminar Series, University of Alabama at Birmingham (Birmingham, AL)  
**June 2004:** National Institute of Neurological Disorders and Stroke, Clinical Trials Program (Bethesda, MD)
8. *Using Internal Pilot Designs with Repeated Measures*  
**August 2005:** Annual Joint Statistical Meetings (Minneapolis, MN)
7. *Sample Size Adjustments Using Internal Pilot Designs for Repeated Measures ANOVA*  
**April 2005:** Department of Biostatistics, University of North Carolina at Chapel Hill (Chapel Hill, NC)
6. *Internal Pilots and Power Adjustments for Controlled Clinical Trials*  
**January 2005:** Center for Aging/VA GRECC, University of Alabama at Birmingham (Birmingham, AL)
5. *Promises and Pitfalls of Modifying the Sample Size during a Study: Adaptive and Internal Pilot Designs*  
**November 2004:** Department of Biostatistics, University of North Carolina at Chapel Hill (Chapel Hill, NC)
4. *Exact and Approximate Methods for Internal Pilots: Beyond Two Group Comparisons*  
**April 2003:** Annual Meeting of the Eastern North American Region (ENAR) of the Biometrics Society (Tampa, FL)
3. *GLUMIP 1.0: Free SAS IML Software for Planning Internal Pilots.*  
**August 2001:** Annual Joint Statistical Meetings (Atlanta, GA)
2. *Is There an Interaction between the ACE I/D and PAI-1 4G/5G Gene Polymorphisms on Risk of Myocardial Infarction?*  
(Joint presentation with Patricia Hebert, Yale, and Jason Moore, Vanderbilt)  
**August 2001:** Joint presentation with Patricia Hebert (Yale) and Jason Moore (Vanderbilt), Section of Cardiovascular Medicine, Department of Internal Medicine, Yale University School of Medicine (New Haven, CT)
1. *Internal Pilot Study Design and Analysis for Gaussian Error Linear Models with Fixed Predictors.*  
**April 2000:** Department of Biostatistics, University of Alabama at Birmingham (Birmingham, AL)  
**October 1999:** Middle Tennessee Chapter, American Statistical Association, (Nashville, TN)  
**September 1999:** Gertrude M. Cox Building Dedication and Statistical Symposium, Research Triangle Institute (Research Triangle Park, NC)  
**August 1999:** Annual Meeting of General Clinical Research Center Statisticians (Baltimore, MD)

## CONTRIBUTED PRESENTATIONS

13. *Adaptive Design for Clinical Trials: Perspectives from an NIH-Sponsored Workshop*  
**May 2011:** Annual Meeting of the Society for Clinical Trials (Vancouver, BC)
12. *Power in Time to Event Trials: Bigger Isn't Always Better*  
**September 2006:** 4<sup>th</sup> Annual SPS3 Investigator's Meeting (San Antonio, TX)
11. *Premature Termination of Clinical Trials*  
**September 2005:** 3<sup>rd</sup> Annual SPS3 Investigator's Meeting (Scottsdale, AZ)
10. *Internal Pilot Designs with Compound Symmetric and Gaussian Repeated Measures*  
**August 2004:** Annual Joint Statistical Meeting (Toronto, Ontario)
9. *Controlling Bias in Internal Pilots with the Univariate Approach to Repeated Measures*  
**March 2004:** Annual Meeting of the Eastern North American Region (ENAR) of the Biometrics Society (Pittsburgh, PA)
8. *Practical Methods for Bounding Test Size with an Internal Pilot Design*  
**August 2003:** Annual Joint Statistical Meeting (San Francisco, CA)
7. *Reporting of Internal Prediction Errors in Case-Control Studies of Genetic Interactions* (Joint presentation with Patricia Hebert, Yale)  
**May 2003:** Annual Meeting of the Society for Clinical Epidemiology and Health Care Research (Vancouver, BC)  
Abstract Published: *Journal of Clinical Epidemiology*, **56(9)**:922-3.
6. *A Comparison of Two Methods for Detecting Interactions among Genetic Polymorphisms in Matched Case-Control Studies*  
**March 2002:** Annual Meeting of the Eastern North American Region (ENAR) of the Biometrics Society (Crystal City, VA)
5. *Internal Pilot for the Univariate Approach to Repeated Measures*  
**March 2001:** Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Charlotte, NC)
4. *Controlling Test Size While Gaining the Benefits of an Internal Pilot Design.*  
**March 2000:** Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Chicago, IL)
3. *The Impact on Power of Controlling Test Size for an Internal Pilot Study.*  
**August 1999:** Annual Joint Statistical Meeting (Baltimore, MD)
2. *Approximations and Bounds on Test Size for an Internal Pilot Study.*  
**March 1999:** Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Atlanta, GA)
1. *Exact Test Size and Power of a Gaussian Error Linear Model for an Internal Pilot Study.*  
**March 1997:** Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Memphis, TN)

## CONTRIBUTED POSTER PRESENTATIONS

7. *The Parkinson's Progression Markers Initiative: A Prospective Biomarkers Study.*  
**May 2011:** Annual Meeting of the Society for Clinical Trials (Vancouver, BC)
6. *Development of an Advanced Clinical Trials Course in a Biostatistics Doctoral Program.*  
**May 2009:** Annual Meeting of the Society for Clinical Trials (Atlanta, GA)

5. *The Metabolic Syndrome and its Association with PAI-1 and t-PA Antigen Levels in a Population-Based Study.* **April 2005:** Annual Conference on Cardiovascular Disease Epidemiology and Prevention (Washington DC)
4. *The Effects of Intentional Weight Loss as a Latent Variable Problem.* **November 2003:** North American Association for the Study of Obesity Annual Scientific Meeting (Ft. Lauderdale, FL)
3. *The Importance of Model Validation in Determining the Clinical Utility of Genetic Interactions on Disease Risk.* **October 2002:** Annual Meeting of the American Society for Human Genetics (Baltimore, MD)
2. *Safety of an Herbal Formulation Including Ephedra Alkaloids Dosed Intermittently or Continuously for Weight Control.* **April 2002:** Annual Meeting of the Federation of American Societies for Experimental Biology (New Orleans, LA)
1. *A Comparison of Two Methods for Detecting Interactions among Genetic Polymorphisms in Matched Case-Control Studies.* **October 2001:** Annual Meeting of the American Society for Human Genetics (San Diego, CA)

### **ABSTRACTS (CO-AUTHORED PRESENTATIONS/POSTERS)**

147. *Analyses of Pharmacokinetics, CSF Exposures and CSF Dopamine and its Metabolite Levels in NILO-PD, A Phase 2A Study of Nilotinib in Moderate to Advanced Parkinson's Disease*  
Merchant KM, Simuni T, Fiske B, **Coffey C**, Matthews H, Wyse RK, Brundin P, Simon DK, Schwarzschild MA, Weiner D, Adams J, Trusso L, Baker L, Kostrzebski M, Ward T, Rafaloff G, and Venuto C on behalf of the NILO-PD Steering Committee  
**October 2019:** Poster Presentation, Society for Neuroscience Annual Meeting (Chicago, IL)
146. *Rituximab Response in Patients with Moderate to Severe Myasthenia Gravis (MG): A Subgroup Analysis of the BeatMG Study*  
Nowak RJ, **Coffey C**, Goldstein JM, Yankey JW, Uribe L, Dimachkie MM, Benatar M, Wolfe GI, Burns T, Pearson B, O'Connor KC, Conwit R, Kissel JT, Hafler DA, Cudkowicz ME, and Barohn RJ on behalf of the NeuroNEXT NN103 BeatMG Study Team  
**October 2019:** Platform Presentation, American Association of Neuromuscular and Electrodiagnostic Medicine Annual Meeting (Austin, TX)
145. *PPMI 2.0 – Transforming PPMI – New Cohorts, New Science – Focus on Prodromal PD*  
Marek K, Siderowf A, Simuni T, **Coffey C**, Foroud T, Arnedo V, Flagg E, Chowdhury S, Kieburtz K, Chahine L, Tanner C, and the Parkinson's Progression Markers Initiative  
**September 2019:** Poster Presentation, Movement Disorders Society Meeting (Nice, France)
144. *Clinical and DAT Imaging Characteristics of Participants with Scans without Evidence of Dopaminergic Deficit (SWEDDs): PPMI Cohort 2 Year Follow-Up*  
Marek K, Simuni T, Siderowf A, Lafontant DE, Caspell-Garcia C, **Coffey C**, Mollenhauer B, Tanner C, Kieburtz K, Chahine L, & Seibyl J on behalf of the PPMI Investigators  
**September 2019:** Poster Presentation, Movement Disorders Society Meeting (Nice, France)
143. *Identifying Incident Cases of Neurodegenerative Parkinsonism in a Large Observational At-Risk Cohort: The PPMI Study*  
Chahine L, Kieburtz K, Brumm M, Caspell-Garcia C, **Coffey C**, Siderowf A, Weintraub D, Tanner C, Foroud T, Galasko D, Mollenhauer B, Simuni T, Marek K, and the Parkinson's Progression Markers Initiative  
**September 2019:** Poster Presentation, Movement Disorders Society Meeting (Nice, France)



142. *Neuropsychiatric Symptoms Over the Initial Lustrum of Parkinson Disease: Common, Increasing, Comorbid & Varied*  
 Weintraub D, Caspell-Garcia C, Simuni T, Cho R, **Coffey C**, Aarsland D, Alcalay R, Barrett M, Chahine LM, Eberling J, Espay A, Hamilton J, Hawkins K, Leverenz J, Litvan I, Richard I, Rosenthal L, Siderow A, York M, and the Parkinson's Progression Markers Initiative  
**September 2019:** Poster Presentation, Movement Disorders Society Meeting (Nice, France)
141. *NILO-PD: A Phase 2A Study of Nilotinib in Patients with Advanced Parkinson's Disease – Study Design and Status Update*  
 Simuni T, Fiske B, Merchant K, **Coffey CS**, Matthews H, Wyse RK, Brundin P, Simon DK, Schwarzschild M, Weiner D, Adams J, Venuto C, Trusso L, Baker L, Kostrzebski M, Ward T, and Rafaloff G on behalf of the NILO-PD PSG Investigators  
**September 2019:** Poster Presentation, Movement Disorders Society Meeting (Nice, France)
140. *Highlights From a Workshop on Enhancing Natural Product Clinical Trials*  
 Pauli G, Kuszak A, Bloss G, Fukagawa N, Jafari M, Walters M, Barrett B, Bushman F, Casper S, Chilton F, **Coffey C**, Feruzzi M, Hopp C, Kiely M, Lakens D, MacMillan J, Meltzer D, Paul J, Pritchett-Corning K, Quinney S, Ross S, Seifried H, Setchell K, Sipes N, Stephens J, Taylor D, Tiriach H, Xi D, Hoffman FA, and Sorkin B  
**July 2019:** Poster Presentation, American Society of Pharmacognosy Meeting (Madison, WI)
139. *Evaluation of Continual Reassessment Method with Lagged Cohort*  
 Wellhaven AE, **Coffey CS**, and Foster EF.  
**May 2019:** Oral Presentation, Society for Clinical Trials Annual Meeting (New Orleans, LA)
138. *Response to Treatment According to Progressive Disease Type: Analysis from a Phase II Progressive MS Trial of Ibudilast*  
 Goodman A, Barnes J, Yankey J, Zahn E, Natarajan S, Bermel R, **Coffey CS**, Klawiter EC, Matsuda K, Naismith RT, & Fox RJ on behalf of the SPRINT-MS Investigators  
**May 2019:** Platform Presentation, American Academy of Neurology Annual Meeting (Philadelphia, PA)
137. *Effect of Ibudilast on Macular Measures in Progressive MS: OCT Analysis from a Phase II Trial*  
 Bermel RA, Barnes J, Yankey J, Zahn E, Natarajan S, **Coffey CS**, Goodman A, Klawiter EC, Matsuda K, Naismith RT, and Fox RJ on behalf of the SPRINT-MS Investigators  
**May 2019:** Poster Presentation, American Academy of Neurology Annual Meeting (Philadelphia, PA)
136. *Effect of Ibudilast on Serum Neurofilament in Progressive MS: Analysis from a Phase II Trial*  
 Fox RJ, Kuhle J, Karafa M, Konig V, Natarajan S, Bermel RA, **Coffey CS**, Goodman A, Klawiter EC, Matsuda K, and Naismith RT on behalf of the SPRINT-MS Investigators  
**May 2019:** Poster Presentation, American Academy of Neurology Annual Meeting (Philadelphia, PA)
135. *NILO-PD: A Phase 2 Study of Nilotinib in Patients with Advanced and Early Parkinson's Disease: Study Design and Status Update*  
 Simuni T, Fiske B, Merchant K, **Coffey CS**, Matthews H, Wyse RK, Brundin P, Simon DK, Schwarzschild M, Weiner D, Adams J, Venuto C, Trusso L, Baker L, Kostrzebski M, Ward T, and Rafaloff G on behalf of the NILO-PD PSG Investigators  
**May 2019:** Poster Presentation, American Academy of Neurology Annual Meeting (Philadelphia, PA)
134. *NILO-PD: A Phase 2A Study of Nilotinib in Patients with Advanced and Early Parkinson's Disease: Study Design and Status Update*  
 Simuni T, Fiske B, Merchant K, **Coffey C**, Matthews H, Wyse R, Brundin P, Simon DK, Schwarzschild M, Weiner D, Venuto C, Trusso L, Baker L, Kostrzebski M, Ward T, and Rafaloff G on behalf of the NILO-PD Steering Committee  
**March 2019:** Poster Presentation, Alzheimer's & Parkinson's Disease Congress (Portugal, Spain)

133. *Irritability in Huntington's Disease: A Phase 2 Exploratory Clinical Trial with a Novel Vasopressin 1a Antagonist SRX246*  
Simon N, Hersch S, Anderson K, Long J, Ecklund D, Costigan M, Thornell B, Gladden C, Coffey C, Cudkowicz M, & Brownstein M  
**December 2018:** Poster Presentation, American College of Neuropsychopharmacology Annual Meeting (Hollywood, FL)
132. *Multisite Tissue and Biofluid Sampling for Alpha-Synuclein in Parkinson's Disease: The Systemic Synuclein Sampling Study (S4)*  
Chahine LM, Beach T, **Coffey C**, Caspell-Garcia C, Adler C, Serrano G, Mosovsky S, Foroud T, Linder C, Riss H, Ecklund D, Seibyl J, Mallya A, Arnedo V, Riley L, Dave K, Jennings D, & Mollenhauer B  
**October 2018:** Poster Presentation, Annual Movement Disorders Society Meeting (Hong Kong)
131. *The National Institute of Neurological Disorders and Stroke Clinical Trials Methodology Course: Outcomes of Trainees After 3 Years*  
Seedorff N, Black J, Conwit R, Lewis R, **Coffey C**, Gutmann L, & Meurer W  
**May 2018:** Poster Presentation, Society for Clinical Trials Annual Meeting (Portland, OR)
130. *A Phase II Trial of Ibudilast in Progressive Multiple Sclerosis*  
Fox RJ, **Coffey CS**, Cudkowicz ME, Gleason T, Goodman A, Klawiter EC, Matsuda K, McGovern M, Conwit R, Naismith R, Ashokkumar A, Barnes J, Ecklund D, Klingner E, Koeppe M, Natarajan S, Thornell B, Yankey J, Bermel RA, Huang X, Lowe MJ, Nakamura K, Narayanan S, Sakaie KE, Debbins JP, Zhou X, Alvarez E, Apperson M, Bashir K, Cohen B, Coyle P, Delgado S, Dewitt D, Flores A, Giesser B, Goldman M, Jubelt B, Lava N, Lynch S, Moses H, Ontaneda D, Perumal J, Racke M, Repovic P, Riley C, Severson C, Shinnar S, Suski V, Weinstock-Guttman B, Yadav V, & Zabeti A on behalf of the NN102/SPRINT-MS Investigators  
**April 2018:** Clinical Trials Plenary Session, American Academy of Neurology Annual Meeting (Los Angeles, CA)
129. *B Cell Targeted Treatment in Myasthenia Gravis (BeatMG) – A Phase 2 Trial of Rituximab in MG: Topline Results*  
Nowak RJ, **Coffey C**, Goldstein JM, Dimachkie MM, Benatar M, Huq SN, Pearson B, Herbelin L, O'Connor KC, Conwit R, Kissel JT, Hafler DA, Cudkowicz ME, & Barohn RJ on behalf of the NeurNEXT NN013 BeatMG Study Team  
**April 2018:** Poster Presentation, American Academy of Neurology Annual Meeting (Los Angeles, CA)
128. *Network for Excellence in Neuroscience Clinical Trials, NeuroNEXT: Update on Success and Five-Year Renewal Application*  
Qidwai J, Kearney Chase M, Ecklund D, Bosch M, Thornell B, **Coffey C**, & Cudkowicz M.  
**March 2018:** Poster Presentation, American Society for Experimental Neurotherapeutics (ASENT) Meeting (Washington, DC)
127. *SPRINT-MS/NN012 Phase II Trial of Ibudilast in Progressive MS: Top-Line Results*  
Naismith R, **Coffey CS**, Cudkowicz ME, Gleason T, Goodman AD, Klawiter EC, Matsuda K, McGovern MM, Conwit R, Ashokkumar A, Ecklund DJ, Klingner E, Koeppe M, Natarajan S, Thornell B, Yankey JW, Bermel R, Huang X, Lowe M, Nakamura K, Narayanan S, Sakaie K, Debbins J, Zhou X, Alvarez E, Apperson ML, Bashir K, Cohen BA, Coyle PK, Delgado S, Dewitt D, Flores A, Giesser B, Goldman M, Jubelt B, Lava N, Lynch SG, Moses H, Ontaneda DD, Perumal JS, Racke MK, Repovic P, Riley CS, Severson CA, Shinnar S, Suski V, Weinstock-Gutman B, Yadav V, Zabeti A, & Fox RJ.  
**February 2018:** Poster Presentation, American Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Annual Meeting (San Diego, CA)
126. *Final Results of the RHAPSODY Trial*  
Lyden P, Coffey CS, Cudkowicz M, Conwit RA, & Pryor KE on behalf of the RHAPSODY Investigators  
**January 2018:** Plenary Presentation at the International Stroke Conference (Los Angeles, CA)

125. *Safety and Tolerability of SRX246 in Irritable/Aggressive Subjects with Huntington's Disease (STAIR): A Phase II Exploratory Clinical Trial*  
 Raulerson S, Berg S, Costigan M, Hersch SM, Anderson KE, Long J, **Coffey CS**, Yankey J, Cudkowicz M, Conwit R, Lungu C, Brownstein MJ, & Simon NG  
**November 2017:** Poster Presentation, Huntington's Study Group Annual Meeting (Denver, CO)
124. *Measurement of Huntington's Irritability and Aggression in the Azevan Pharmaceuticals-NeuroNEXT STAIR Study*  
 Anderson K, Hersch S, Long J, Cudkowicz M, **Coffey C**, Yankey J, Costigan M, Raulerson S, Berg S, Conwit R, Lungu C, Brownstein M, & Simon L.  
**November 2017:** Poster Presentation, Huntington's Study Group Annual Meeting (Denver, CO)
123. *SPRINT-MS/NN012 Phase II Trial of Ibudilast in Progressive MS: Top-Line Results*  
 Fox RJ, **Coffey CS**, Cudkowicz ME, Gleason T, Goodman A, Klawiter EC, Matsuda K, McGovern M, Conwit R, Naismith R, Ashokkumar A, Ecklund D, Koepp M, Long J, Natarajan S, Skaramagas T, Thornell B, Yankey J, Bermel R, Huang X, Lin J, Lowe M, Nakamura K, Narayanan S, Sakaie KE, Debbins JP, Zhou X, Alvarez E, Apperson M, Bashir K, Cohen B, Coyle P, Delgado S, Dewitt D, Flores A, Giesser B, Goldman M, Jubelt B, Lava N, Lynch S, Moses H, Ontaneda D, Perumal J, Racke M, Repovic P, Riley C, Severson C, Shinnar S, Suski V, Weinstock-Gutman B, Yadav V, & Zabeti A on behalf of the NN102/SPRINT-MS Study Investigators.  
**October 2017:** Plenary Presentation at European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) Annual Meeting (Paris, France)
122. *Biological Analyses of PPMI Samples*  
 Mollenhauer B, Caspell-Garcia CJ, **Coffey CS**, Taylor P, Shaw LM, Trojanowski JQ, Singleton A, Naito A, Reimer A, Frasier M, Marek K, and Galasko D for the Parkinson Progression Marker Initiative  
**October 2017:** PD Therapeutics Conference (New York, NY)
121. *Feasibility and Safety of Multisite Tissue and Biofluid Sampling for Alpha-Synuclein in Parkinson's Disease: The Systemic Synuclein Sampling Study (S4)*  
 Linder C, Mollenhauer B, **Coffey C**, Beach T, Foroud T, Adler C, Riss H, Ecklund D, Caspell-Garcia C, Dave K, Deshpande S, Lasch S, Arnedo V, Riley L, Kopil C, Jennings D, & Chahine L  
**June 2017:** Poster Presentation, Annual Movement Disorders Society Meeting (Vancouver, BC)
120. *Network for Excellence in Neuroscience Clinical Trials, NeuroNEXT: Pre-Award Process and Experiences*  
 Foster E, Mahoney K, Ecklund D, Kearney Chase M, Bosch M, Thornell B, **Coffey C** & Cudkowicz M  
**May 2017:** Poster Presentation, Society for Clinical Trials Annual Meeting (Liverpool, UK)
119. *Feasibility and Safety of Multisite Tissue and Biofluid Sampling for Alpha-Synuclein in Parkinson's Disease: The Systemic Synuclein Sampling Study (S4)*  
 Linder C, Mollenhauer B, **Coffey C**, Beach TG, Foroud T, Adler CH, Riss H, Ecklund D, Caspell-Garcia C, Dave KD, Deshpande S, Lasch S, Arnedo V, Riley L, Jennings D, & Chahine L  
**April 2017:** Poster Presentation, American Academy of Neurology Annual Meeting (Boston, MA)
118. *The Systemic Synuclein Sampling Study*  
 Mollenhauer B, **Coffey C**, Beach TG, Foroud T, Adler CH, Ecklund D, Dave KD, Deshpande S, Lasch S, Arnedo V, Riley L, Jennings D, & Chahine L.  
**March 2017:** Poster Presentation, Alzheimer's & Parkinson's Disease Congress (Vienna, Austria)
117. *Network for Excellence in Neuroscience Clinical Trials, NeuroNEXT: Increasing Efficiency in Clinical Trials*  
 Kearney Chase M, Ecklund D, Bosch M, Thornell B, **Coffey C**, & Cudkowicz M.  
**October 2016:** Poster Presentation, American Neurological Association Annual Meeting (Baltimore, MD)

116. *Longitudinal Evolution of Possible REM Sleep Behavior Disorder in Early Parkinson's Disease*  
Oertel W, Simuni T, Caspell-Garcia C, Long J, **Coffey CS**, Iranzo A, Mayer G, Chahine L, Lasch S, & Marek K on behalf of the PPMI Sleep Working Group  
**June 2016:** International Movement Disorders Congress (Berlin, Germany)
115. *The Systemic Synuclein Sampling Study (S4)*  
Jennings D, **Coffey C**, Beach T, Foroud T, Adler CH, Mollenhauer B, Seibyl J, Ecklund D, Lasch S, Arnedo V, & Kopil C  
**June 2016:** International Movement Disorders Congress (Berlin, Germany)
114. *Longitudinal Cerebrospinal Fluid Biomarkers in Early Parkinson's Disease and Healthy Controls*  
Mollenhauer B, Caspell-Garcia CJ, **Coffey CS**, Taylor P, Shaw LM, Trojanowski JQ, Singleton A, Frasier M, Marek K, & Galasko DR  
**June 2016:** International Movement Disorders Congress (Berlin, Germany)
113. *Baseline Prevalence and Longitudinal Evolution of Non-Motor Symptoms in Early Parkinson's Disease – PPMI Cohort*  
Simuni T, Weintraub D, Caspell-Garcia C, Walker M, **Coffey CS**, Lasch S, Tanner C, Jennings D, Kiebertz K, & Marek K on behalf of the PPMI Investigators  
**June 2016:** International Movement Disorders Congress (Berlin, Germany)
112. *Longitudinal Evolution of Excessive Daytime Sleepiness in Early Parkinson's Disease*  
Simuni T, Caspell-Garcia C, Long J, **Coffey CS**, Oertel W, Lasch S, & Marek K on behalf of the PPMI Sleep Working Group  
**June 2016:** International Movement Disorders Congress (Berlin, Germany)
111. *Clinical and Biological Predictors of Time to Initiation of Symptomatic Therapy in Early Parkinson's Disease*  
Simuni T, Long J, Caspell-Garcia C, **Coffey CS**, Lasch S, Tanner C, Jennings D, Kiebertz K, & Marek K on behalf of the PPMI Investigators  
**June 2016:** International Movement Disorders Congress (Berlin Germany)
110. *Physician-Pharmacist Collaboration: Overcoming Socioeconomic Barriers*  
Gums TH, Anderegg MD, Uribe L, **Coffey C**, and Carter BL.  
**May 2016:** Annual Meeting of the American Society for Hypertension (New York, NY)
109. *Selecting Patients for Intra-Arterial Therapy in the Context of a Clinical Trial for Neuroprotection*  
Lyden P, Weymer S, **Coffey C**, Cudkowicz M, Fisher M, Haley EC, Khatri P, Saver J, Levine S, Levy H, Pryor K, Rymer M, and Wechsler L.  
**February 2016:** International Stroke Conference (Los Angeles, CA)
108. *A Phase 2 Trial of Rituximab in Myasthenia Gravis: Study Update*  
Nowak RJ, **Coffey C**, Goldstein JM, Dimachkie M, Benatar M, O'Connor KC, Kissel J, Hafler DA, Barohn R, and Cudkowicz for the NeuroNEXT NN103 Study Team.  
**September 2015:** Annual Meeting of the American Neurological Association (Chicago, IL)
107. *Can We Reliably Establish Parkinson's Disease Subtypes in De Novo Patients: Follow Up Results from the PPMI Study*  
Simuni T, Caspell-Garcia C, **Coffey C**, Lasch S, Jennings D, Tanner C, Kiebertz K, and Marek K.  
**June 2015:** 19th Int. Congress of Parkinson's Disease and Movement Disorders (San Diego, CA)
106. *Initial Results from the NeuroNEXT SMA Infant Biomarker Study*  
Kolb SJ, **Coffey CS**, Yankey JW, Arnold D, Rutkove SB, Bartlett A, Rensch S, Wang S, Snyder PJ, Prior TW, and Kissel JT for the NeuroNEXT Clinical Trial Network and on behalf of the NN101 SMA Biomarker Investigators.  
**June 2015:** Cure SMA Annual Researcher Meeting (Kansas City, MO)

105. *Including Uncertainty in the Target Probability of Dose Limiting Toxicity in Phase I/II Studies with a Dose Finding Component*  
Foster E, Thomann MA, and **Coffey CS**.  
**May 2015:** Society for Clinical Trials Annual Meeting (Washington, DC)
104. *The NINDS Clinical Trials Methodology Course: Approach and Lessons from Year 1*  
Meurer WJ, Mawocha S, Conwit R, Lewis R, **Coffey C**, and Gutmann L.  
**May 2015:** Society for Clinical Trials Annual Meeting (Washington, DC)
103. *The Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT) Protocol Working Group Design Phase Experiences*  
Foster E, **Coffey CS**, Cudkowicz ME, Ecklund DJ, Bosch MJ, Thornell BJ, Kearney M, Littizzio E, Ashokkumar A, and Mahoney K  
**May 2015:** Society for Clinical Trials Annual Meeting (Washington, DC)
102. *NN102/SPRINT-MS Phase II Trial of Ibudilast in Progressive MS: Baseline Characteristics*  
Fox R, **Coffey C**, Cudkowicz M, Gleason T, Goodman A, Klawiter E, Matsuda K, McGovern M, McNeil E, Naismith R, and Yankey J.  
**April 2015:** Annual Meeting of the American Academy of Neurology (Washington, DC)
101. *Initial Results from the NeuroNEXT SMA Infant Biomarker Study*  
Kolb SJ, **Coffey CS**, Arnold WD, Rutkove SB, Bartlett A, and Kissel JT from the NeuroNEXT Clinical Trial Network and on behalf of the NN101 SMA Biomarker Investigators  
**April 2015:** Annual Meeting of the American Academy of Neurology (Washington, DC)
100. *Network for Excellence in Neuroscience Clinical Trials, NeuroNEXT: Increasing Efficiency in Clinical Trial Management*  
Kearney M, Ecklund D, Bosch M, Thornell B, McNeil E, Cordell J, **Coffey C**, and Cudkowicz M  
**April 2015:** Annual Meeting of the American Academy of Neurology (Washington, DC)
99. *Multicenter Evaluation of Parkinson's Disease Progression using 123-I-Ioflupane SPECT: Update from the Parkinson's Progression Marker Initiative Trial*  
Seibyl J, Jennings D, **Coffey C**, and Marek K  
**June 2014:** 18<sup>th</sup> Int. Congress of Parkinson's Disease and Movement Disorders (Stockholm, Sweden)
98. *Excessive Day Time Sleepiness Is Not Part of Parkinson's Disease Disability in De Novo Patients: Results from the PPMI Study*  
Simuni T, Caspell C, **Coffey C**, Chahine LC, Lasch S, Oertel W, and Marek K for the PPMI Investigators.  
**June 2014:** 18<sup>th</sup> Int. Congress of Parkinson's Disease and Movement Disorders (Stockholm, Sweden)
97. *Degeneration of Corticostriatal Fibers in Parkinson's Disease and Their Differential Relations to Cognitive and Motor Deficits*  
Zhang Y, Wu K, Buckley S, Mendick S, Seibyl J, Foster E, **Coffey C**, Marek K, and Schuff N for the Parkinson's Progression Markers Initiative (PPMI).  
**June 2014:** 18<sup>th</sup> Int. Congress of Parkinson's Disease and Movement Disorders (Stockholm, Sweden)
96. *Cognitive Performance and Psychiatric Symptoms in De Novo, Untreated Parkinson's Disease: Results from the PPMI Study*  
Weintraub D, Simuni T, **Coffey C**, Caspell-Garcia C, Foster E, Barone P, Leverenz J, Burn D, Eberling J, Chahine L, Litvan T, Troyer M, Siderowf A, Aarsland D, and Hawkins K for the PPMI Cognitive Behavioral Working Group  
**June 2014:** 18<sup>th</sup> Int. Congress of Parkinson's Disease and Movement Disorders (Stockholm, Sweden)
95. *Can We Reliably Establish Parkinson's Disease Subtypes in De Novo Patients: Results from the PPMI Study*  
Simuni T, **Coffey C**, Uribe L, Lasch S, Jennings D, Tanner C, and Marek K for the PPMI Investigators  
**June 2014:** 18<sup>th</sup> Int. Congress of Parkinson's Disease and Movement Disorders (Stockholm, Sweden)

94. *Coordinating Center Support Required for an Academic Central IRB: The NeuroNEXT Network Experience*  
Kearney M, Flynn K, Huq S, Ashokkumar A, Simpson E, McCourt M, Ecklund D, Bosch M, **Coffey C**, and Cudkowicz M.  
**May 2014:** Society for Clinical Trials Annual Meeting (Philadelphia, PA)
93. *The NeuroNEXT Experience of Patient Engagement in Protocol Development*  
Kearney M, Thornell B, Mahoney K, Ecklund D, **Coffey C**, and Cudkowicz M  
**May 2014:** Society for Clinical Trials Annual Meeting (Philadelphia, PA)
92. *Assessment of Site Feasibility: The NeuroNEXT Network Experience*  
Kearney M, McCourt M, Huq S, Strodel R, Thornell B, Ecklund D, Bosch M, **Coffey C**, and Cudkowicz M.  
**May 2014:** Society for Clinical Trials Annual Meeting (Philadelphia, PA)
91. *Simulation Study to Assess an A Priori Decision Algorithm for a Randomized Three-Armed Clinical Trial*  
Zahn E and **Coffey C**  
**May 2014:** Society for Clinical Trials Annual Meeting (Philadelphia, PA)
90. *Network for Excellence in Neuroscience Clinical Trials, NeuroNEXT: Increasing Efficiency in Clinical Trial Management*  
Kearney M, Ecklund D, Bosch M, Thornell B, McNeil E, Koroshetz W, Kaufmann P, **Coffey C**, Cudkowicz M  
**April 2014:** Annual Meeting of the American Academy of Neurology (Philadelphia, PA)
89. *Risk of Stroke and Vascular Events and Response to Antiplatelet Therapy in Young Adults with Recent Lacunar Strokes: The SPS3 Study*  
Pikula A, **Coffey CS**, Lau HW, White CL, Kase CS, and Benavente O  
**February 2014:** International Stroke Congress (San Diego, CA)
88. *Benefits of Clinical Trial Participation for Risk Factor Control: Experience from the SPS3 Study*  
Lau H, White C, **Coffey C**, Romero J, Pikula A, Babikian V, and Benavente O  
**February 2014:** International Stroke Congress (San Diego, CA)
87. *Rapid Rollout of a Pediatric Migraine Prevention Study Conducted in Academic Research Centers*  
Korbee L, Powers S, Hershey A, Chamberlin L, Allen J, LeCates S, White S, Kroner J, Sullivan S, **Coffey C**, and Ecklund D.  
**November 2014:** International Headache Congress (Scottsdale, AZ)
86. *123-I Ioflupane SPECT Measures of Parkinson Disease Progression in the Parkinson Progression Marker Initiative (PPMI) Trial*  
Seibyl JP, Jennings D, Grachev, I, **Coffey C**, & Marek K on behalf of the PPIM Investigators  
**June 2013:** Annual Meeting of the Movement Disorders Society (Sydney, Australia)
85. *Relationship Between Serum Urate and Clinical Features in Early Parkinson's Disease: PPMI Baseline Data*  
Constantinescu R, Jennings D, Foster ED, Auinger P, **Coffey CS**, & Marek K for the Parkinson's Progression Markers Initiative  
**June 2013:** Annual Meeting of the Movement Disorders Society (Sydney, Australia)
84. *Cognitive Performance and Psychiatric Symptoms in De Novo, Untreated Parkinson's Disease: Results from the PPMI Study*  
Weintraub D, Jennings D, Foster ED, Auinger P, **Coffey CS**, & Marek K for the Parkinson's Progression Markers Initiative  
**June 2013:** Annual Meeting of the Movement Disorders Society (Sydney, Australia)

83. *Rapid Rollout of a Pediatric Migraine Prevention Study Conducted in Academic Research Centers*  
Korbee L, Powers S, Hershey A, Chamberlin L, Allen J, LeCates S, White S, Kroner J, Sullivan S,  
**Coffey C**, and Ecklund D  
**June 2013:** International Headache Congress (Boston, MA)
82. *Internal Pilot Design for Cluster Randomized Trials with Unequal Cluster Sizes*  
Ranjan A, McClure LA, and **Coffey CS**  
**May 2013:** Society for Clinical Trials Annual Meeting (Boston, MA)
81. *Network for Excellence in Neuroscience Clinical Trials, NeuroNEXT: Concept to Implementation*  
Kearney M, Ecklund D, Simpson E, Bosch M, Sweet B, Jackson K, Mahoney K, McCourt M, Thornell  
B, Titus S, Soodoo N, O'Brien J, Gloer K, Costigan M, Logsdan-Sackett N, Huff T, Shefner J, Staley K,  
Guttman L, Clarke W, Torner J, Long J, Chaloner K, Bayman E, McNeil E, Kaufmann P, Koroshetz W,  
Cudkowicz M, and **Coffey CS**  
**March 2013:** American Academy of Neurology Annual Meeting (San Diego, CA)
80. *The Coalition Against Major Diseases: Dopamine Transporter Imaging as an Enrichment Biomarker to  
Enable Parkinson's Disease Clinical Trials*  
Gordon M, Stephenson D, **Coffey C**, Cole PE, Comery TA, Grachev I, Grosset D, Harbron C,  
Kuoppamaki M, Lindstedt K, Meibach R, Marek K, Matthews D, Romero K, Russell D, Seibyl J, Sherer  
T, Stark Y, Subramaniam R, and Walton M for the Coalition Against Major Diseases (CAMD)  
**March 2013:** American Academy of Neurology Annual Meeting (San Diego, CA)
79. *Factors Affecting Time to Achieve Blood Pressure Targets in the Secondary Prevention of Small  
Subcortical Strokes (SPS3) Trial*  
Szychowski JM, McClure LA, White CL, Pergola PE, Benavente O, and **Coffey CS**  
**February 2013:** International Stroke Conference (Honolulu, HI)
78. *Increasing the Sample Size in the Secondary Prevention of Small Subcortical Strokes (SPS3) Study:  
What Did We Gain?*  
McClure LA, Szychowski JM, Benavente O, Hart RG, and **Coffey CS**  
**February 2013:** International Stroke Conference (Honolulu, HI)
77. *The NIHSS Supplementary Motor Scale: A Valid Tool for Multidisciplinary Recovery Trials*  
Leira EC, **Coffey CS**, Jorge RE, Morton SM, Froehler MT, Davis PH, and Adams HP  
**February 2013:** International Stroke Conference (Honolulu, HI)
76. *Factors Affecting Time to Achieve Blood Pressure Targets in the Secondary Prevention of Small  
Subcortical Strokes (SPS3) Trial*  
Szychowski JM, McClure LA, White CL, Pergola PE, Benavente OR, and **Coffey CS**  
**February 2013:** International Stroke Conference (Honolulu, HI)
75. *Adaptive Designs for Comparative Effectiveness Trials*  
Kairalla JA, **Coffey CS**, Thomann MA, and Muller KE  
**August 2012:** Joint Statistical Meetings (San Diego, CA)
74. *CSF Biomarkers in Early Parkinson's Disease: Predictors of Risk for Disease Progression*  
Kang JH, Chen-Plotkin A, Irwin D, Siderowf A, Caspell C, **Coffey C**, Taylor P, Frasier M, Marek K,  
Trojanowski J, Shaw LM, and the Parkinson's Progression Marker Initiative  
**July 2012:** Alzheimer's Association International Conference (Vancouver, BC)
73. *Diurnal and Intersubject Variability of Cerebrospinal Fluid Biomarkers in Parkinson's Disease and  
Healthy Volunteers*  
Frasier MA, Marek K, Taylor P, Caspell C, **Coffey C**, Ereshefsky L, Yen M, and Sherer T  
**June 2012:** Annual Meeting of the Movement Disorders Society (Dublin, Ireland)

72. *Association Between CSF Biomarkers and Clinical Phenotype of Early Parkinson's Disease*  
Kang JH, Caspell C, **Coffey C**, Taylor P, Frasier M, Marek K, Trojanowski JQ, Shaw LM, and the Parkinson's Progression Marker's Initiative  
**June 2012:** Annual Meeting of the Movement Disorders Society (Dublin, Ireland)
71. *Adaptive Designs for Clinical Comparative Effectiveness Research: Are We Ready?*  
Kairalla JA, Thomann MA, **Coffey CS**, Shorr RI, and Muller KE.  
**May 2012:** Society for Clinical Trials Annual Meeting (Miami, FL).
70. *NeuroNEXT: Developing Infrastructure for Phase 2 Clinical Trials in Neurological Disorders.*  
Ecklund D, Kearney M, **Coffey CS**, Cudkowicz M, and McNeil E  
**May 2012:** Society for Clinical Trials Annual Meeting (Miami, FL).
69. *A Class of Two-Stage Internal Pilot with Interim Analysis Designs for Two Group Comparative Effectiveness Trials.*  
Kairalla JA, Thomann MA, **Coffey CS**, and Muller KE.  
**March 2012:** Annual Meeting of the Eastern North American Region (ENAR) of the Biometric Society (Washington, DC).
68. *Diurnal Fluctuations of Parkinson's Disease Biomarkers in Healthy Volunteers*  
Frasier M, Marek K, Schlossmacher M, Yen M, Taylor P, Caspell C, and **Coffey C**  
**June 2011:** International Congress of Parkinson's Disease and Movement Disorders (Toronto, ON)
67. *Some Strategies for Report Generation by Biostatisticians in Clinical Trials.*  
Yankey J, **Coffey CS**, and Clarke WR.  
**May 2011:** Society for Clinical Trials Annual Meeting (Vancouver, BC)
66. *Predictors of Blood Pressure Control at 6 and 12 Months in the Secondary Prevention of Small Subcortical Strokes (SPS3) Study*  
Hornung LN, Szychowski J, White CL, Graves JW, Pergola PE, McClure LA, **Coffey CS**, Hart RG, and Benavente OR.  
**May 2011:** Society for Clinical Trials Annual Meeting (Vancouver, BC).
65. *Benefits of Clinical Trial Participation for Risk Factor Control: Experience from the SPS3 Study*  
Lau H, White C, **Coffey C**, Romero J, Pikula A, Babikian V, Kase C, and Benavente O  
**February 2011:** International Stroke Conference (New Orleans, LA)
64. *The Use of an Unplanned Adaptive Design in an NIH-Sponsored Stroke Prevention Trial*  
McClure LA, Szychowski JM, Benavente O, Hart RG, Conwit R, and **Coffey CS**  
**February 2011:** International Stroke Conference (Los Angeles, CA)
63. *Achieving the Benefits of Both an Internal Pilot and Interim Analysis in Small Samples*  
Kairalla JA, Muller KE, and **Coffey CS**  
**August 2010:** Joint Statistical Meetings (Vancouver, BC).
62. *The Parkinson's Progression Marker's Initiative: A Prospective Biomarkers Study*  
Frasier M, Chowdury S, Sherer T, Eberling J, Meunier C, Ravina B, Siderowf A, Scherzer C, Jennings D, Tanner C, Kieburtz K, **Coffey C**, Poewe W, Mollenhauer B, Seibyl J, Toga A, Ansbach A, De Blasio P, Piovella M, Trojanowski J, Shaw L, Singleton A, and Marek K  
**June 2010:** Annual Movement Disorders Society Meeting (Buenos Aires, Argentina).
61. *Survey on the Use of Adaptive Designs in the Journal of the American Medical Association (2007-2008)*  
Mbowe O, Birkner T, and **Coffey CS**.  
**May 2010:** Society for Clinical Trials Annual Meeting (Baltimore, MD)
60. *The Effect of an Unplanned Sample Size Re-Estimation on the Type I Error Rate*  
McClure LA, Szychowski JM, Benavente O, and **Coffey CS**  
**May 2010:** Society for Clinical Trials Annual Meeting (Baltimore, MD)



59. *Achieving the Benefits of an Internal Pilot with Interim Analysis While Controlling Type I Errors for Gaussian Linear Models*  
Kairalla JA, Muller KE, and **Coffey CS**  
**August 2009:** Joint Statistical Meetings (Washington, DC).
58. *Ambulatory Blood Pressure as Related to White Matter Hyperintensity*  
Howard KP and **Coffey CS**  
**May 2009:** Society for Clinical Trials Annual Meeting (Atlanta, GA)
57. *Monitoring Futility in Two-by-Two Factorial Studies*  
McClure LA, Howard G, and **Coffey CS**  
**May 2009:** Society for Clinical Trials Annual Meeting (Atlanta, GA).
56. *Factors Affecting Time to In-Target Blood Pressure Status in a Multicenter International Trial.*  
Szychowski J, McClure L, White C, Pergola P, Graves J, Hart R, Benavente O, and **Coffey CS**  
**May 2009:** Society of Clinical Trials Annual Meeting (Atlanta, GA).
55. *Predicting Survival in Pulmonary Arterial Hypertension Using the REVEAL Database*  
Benza RL, Foreman AJ, Prucka WR, Gomberg-Maitland M, Frantz RP, Miller DP, **Coffey CS**, Elliott CG, and McGoon MD.  
**May 2009:** Annual Meeting of the American Thoracic Society (San Diego, CA).
54. *Are Lacunar Strokes Different in Hispanic Patients? The SPS3 Study.*  
Benavente O, Del Brutto O, Arauz A, Ruiz-Sandoval JL, Roldan A, Szychowski J, Peri K, **Coffey CS**, White C, and Hart RG. **February 2009:** American Stroke Association Annual Meeting (San Diego, CA).
53. *Cytokine SNP's and Their Relationship to the Development of Peripartum Cardiomyopathy.*  
Pekarek D, Barchue J, Grenett H, Biggio J, Robin N, **Coffey CS**, and Benza R.  
**January 2009:** Annual Meeting of the Society for Maternal and Fetal Medicine (San Diego, CA).
52. *Estimating Predictive Error for Left- and Right-Censored Survival Data with Time-Varying Covariates.*  
Prucka WR and **Coffey CS**  
**August 2008:** Joint Statistical Meetings (Denver, CO).
51. *GLUMIP 2.0: SAS/IML Software for Planning Internal Pilots.*  
Kairalla JA, **Coffey CS**, and Muller KE. **August 2008:** Joint Statistical Meetings (Denver, CO).
50. *Potential Outcomes Applied to an Intentional Weight Loss Application.*  
Supapkorn T, Gadbury GL, **Coffey CS**, Keith SW, and Allison DB.  
**August 2008:** Joint Statistical Meetings (Denver, CO).
49. *ET-1 Polymorphism and Functional Capacity Interactions in PAH Patients Treated with Endothelin Antagonists.*  
Benza R, Prucka W, Frost A, Gomberg M, Lawrence E, Barchue J, **Coffey CS**, and Grenett H.  
**May 2008:** American Thoracic Society Annual Meeting (Toronto, Canada)
48. *eNOS Polymorphism and 6MWD Interactions in PAH Patients on Endothelin Antagonists.*  
Benza R, Prucka W, Torbicki A, Pulido R, Langleben D, Barchue J, **Coffey CS**, and Grenett H.  
**May 2008:** American Thoracic Society Annual Meeting (Toronto, Canada)
47. *Atypical Lacunar Syndromes: Same Disease as Classical Lacunar Infarcts? The Secondary Prevention of Small Subcortical Strokes (SPS3) Study.*  
Benavente OR, Arboix A, Bazan C, Rubio F, **Coffey CS**, McClure L, Nair N, Roldan A, White C, and Hart R.  
**May 2008:** European Stroke Meeting (Nice, France)

46. *HsCRP and SAA among Patients with Lacunar Stroke: Preliminary Findings from the Levels of Inflammatory Markers in Treatment of Ischemic Stroke (LIMITS) Study.*  
Luna J, McClure LA, Szychowski JM, **Coffey CS**, Benavente O, White C, Roldan A, Liu K, Wang H, Fink DJ, and Elkind MSV.  
**April 2008:** American Academy of Neurology Meeting (Chicago, IL)
45. *A Two-Stage Procedure for Factorial Designs Utilizing a Formal Futility Rule.*  
Nair NK and **Coffey CS**  
**March 2008:** Annual Meeting of the Eastern North American Region (ENAR) of the Biometrics Society (Alexandria, VA)
44. *GLMIP 1.0: SAS/IML Software for Planning Repeated Measures Internal Pilots.*  
Muller KE, **Coffey CS**, Kairalla JA, and Johnson JL.  
**March 2008:** Annual Meeting of the Eastern North American Region (ENAR) of the Biometrics Society (Alexandria, VA)
43. *Adjusting for Covariates in the Analysis of Microarray and Other High Dimensional Biological Data.*  
Chen L, Beasley MB, **Coffey CS**, and Page GP.  
**March 2008:** Annual Meeting of the Eastern North American Region (ENAR) of the Biometrics Society (Alexandria, VA)
42. *Internal Pilot Designs for Observational Studies.*  
Gurka MJ and **Coffey CS**  
**March 2008:** Annual Meeting of the Eastern North American Region (ENAR) of the International Biometric Society (Alexandria, VA)
41. *Internal Pilot with Interim Analysis for Single Degree of Freedom Hypothesis Tests*  
Kairalla JA, Muller KE, and **Coffey CS**  
**March 2008:** Annual Meeting of the Eastern North American Region (ENAR) of the International Biometric Society (Alexandria, VA)
40. *Single vs. Multiple Lacunar Infarcts: Are They Caused by Different Diseases? The SPS3 Study.*  
Benavente O, Bazan C, Nair N, McClure L, **Coffey C**, Pretel J, Krupinski Y, Vaishnav A, Hart R, and Roldan A.  
**February 2008:** American Stroke Association Annual Meeting (New Orleans, LA)
39. *An Internal Pilot Study with Interim Analysis for Gaussian Linear Models*  
Kairalla J, Muller KE, and **Coffey CS**  
**August 2007:** Annual Joint Statistical Meetings (Salt Lake City, UT)
38. *Small Sample Properties of Information-Based Monitoring*  
Sawrie D and **Coffey CS**.  
**August 2007:** Annual Joint Statistical Meetings (Salt Lake City, UT)
37. *Bayesian Analysis of the Effect of Intentional Weight Loss on Mortality Rate*  
Yi N, Ding S, Keith SW, **Coffey CS**, and Allison DB.  
**August 2007:** Annual Joint Statistical Meetings (Salt Lake City, UT)
36. *Wavelet-Based Modeling of Clinical Outcomes Using Diffusion Tensor Image Data*  
Prucka W, **Coffey CS**, Cutter G, and Reich DS.  
**August 2007:** Annual Joint Statistical Meetings (Salt Lake City, UT)
35. *Internal Pilot Designs and Mixed Models*  
Gurka M, **Coffey CS**, and Muller KE.  
**August 2007:** Annual Joint Statistical Meetings (Salt Lake City, UT)
34. *Monitoring Serious Adverse Events via a Web-Based System*  
Guyton F, Allcorn C, Stern B, McCarthy S, and **Coffey CS**.  
**May 2007:** Society for Clinical Trials Annual Meeting (Montreal, Quebec, Canada)

33. *TGF-Beta Polymorphisms, Gender, Age, and Their Effect on Acute Cardiac Rejection.*  
Pekarek D, **Coffey CS**, Barchue J, Grennett H, Tallaj J, Rayburn B, Kirklin J, and Benza RL.  
**April 2007:** Annual Meeting of the International Society for Heart and Lung Transplantation (San Francisco, CA)
32. *Relationship between u-PA and TGF-Beta Genotypes and Allograft Coronary Disease.*  
Pekarek D, **Coffey CS**, Barchue J, Grennett H, Tallaj J, Rayburn B, and Benza RL.  
**April 2007:** Annual Meeting of the International Society for Heart and Lung Transplantation (San Francisco, CA)
31. *A Wavelet Based Method for Determining Persistent DNA Copy Number Variation Across Multiple Subjects.*  
Prucka WR and **Coffey CS**  
**March 2007:** Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Atlanta, GA)
30. *Internal Pilot Design with Interim Analysis.*  
Kairalla JA, Muller KE, **Coffey CS**.  
**March 2007:** Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Atlanta, GA)
29. *Preemptive Power and the Consulting Statistician.*  
Sawrie DF and **Coffey CS**  
**March 2007:** Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Atlanta, GA)
28. *DWI Overestimates the Ultimate Size of Lacunar Infarcts.*  
Benavente O, Bazan C, Tonarelli S, Pergola G, McClure L, **Coffey C**, and Hart RG.  
**February 2007:** American Stroke Association Annual Meeting (San Francisco, CA)
27. *Orthostatic Hypotension (OH) at Six and Twelve Months in the Secondary Prevention of Small Subcortical Strokes (SPS3) Study.*  
Graves JW, Wochos DN, and **Coffey CS** for the SPS3 Study Group.  
**October 2006:** Annual Meeting of the International Society of Hypertension (Fukuoka, Japan)
26. *Predictors of Achievement of Assigned Blood Pressure Target at Six Months and One Year in the SPS3 Study.*  
Graves JW, Pergola PE, Benavente OR, Hart RG, **Coffey CS**, and White CL for the SPS3 Study Group.  
**October 2006:** Annual Meeting of the International Society of Hypertension (Fukuoka, Japan)
25. *Secondary Prevention of Small Subcortical Strokes with BP Lowering and Antiplatelet Therapies: A 2x2 Factorial Trial (SPS3).*  
Grimm R, Pergola P, Hart R, Anderson D, Benavente O, White C, Graves J, **Coffey C**, and Brauer D.  
**October 2006:** Annual Meeting of the International Society of Hypertension (Fukuoka, Japan)
24. *GLUMIP 2.0: Free SAS/IML Software for Planning Internal Pilots.*  
Kairalla JA, **Coffey CS**, Muller KE.  
**August 2006:** Annual Joint Statistical Meeting (Seattle, WA)
23. *Monitoring Futility in 2x2 Factorial Studies.*  
McClure LA, **Coffey CS**, and Howard GH.  
**August 2006:** Annual Joint Statistical Meeting (Seattle, WA)
22. *Predictive Value of Adipokines for Development of Cardiovascular Events in a Population-Based Cohort.*  
Wolffenbuttel BHR, van Beek AP, Hebert PR, **Coffey CS**, and de Jong PE.  
**June 2006:** Annual Meeting of the American Diabetes Association (Washington, DC)

21. *Treatment of Hypertension with Epithelial Sodium Channel Inhibitors Combined with Hydrochlorothiazide Reduces Sudden Coronary Death and Total Coronary Mortality.*  
Hebert PR, Murry KT, Rottman JN, **Coffey CS**, Byrne DW, McCormack VA, Fagard RH, Meade TW, and Oates JA.  
**November 2005:** Annual Meeting of the American Heart Association (Dallas, TX)
20. *African-Americans with Kidney Disease Have Better Survival Than Whites After Acute Myocardial Infarction.*  
Newsome BB, McClellan WM, Allison JJ, Kiefe CI, **Coffey CS**, and Warnock DG.  
**November 2005:** Annual Meeting of American Society of Nephrology (Philadelphia, PA)
19. *African-Americans Have a Greater Risk of End-Stage Renal Disease Following Hospitalization for Acute Myocardial Infarction.*  
Newsome BB, Warnock DG, Allison JJ, Eggers P, Kiefe CI, Collins A, Chen S, **Coffey CS**, and McClellan WM.  
**November 2005:** Annual Meeting of American Society of Nephrology (Philadelphia, PA)
18. *Quality of Blood Pressure Measurement in the SPS3 (Secondary Prevention of Small Subcortical Strokes) Study.*  
Graves JW and **Coffey CS** for the SPS3 Study Group.  
**May 2005:** Annual Meeting of American Society of Hypertension (San Francisco, CA)
17. *GLUMIP 2.0: Free SAS/IML Software for Planning Internal Pilots.*  
Kairalla JA, **Coffey CS**, Muller KE.  
**March 2005:** Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Austin, TX)
16. *Repeated Measures for Gaussian Multivariate Linear Models: A Tutorial.*  
Simpson SL, **Coffey CS**, Muller KE.  
**March 2005:** Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Austin, TX)
15. *Avoiding Test Size Bias Due to Internal Pilots with Gaussian Repeated Measures.*  
Clement ME, **Coffey CS**, Muller KE.  
**March 2005:** Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Austin, TX)
14. *Toward Unbiased Estimation of the Effects of Risk Factors in the Presence of Latent Confounders Estimated with Error by Simulation-Extrapolation in Cox Proportional Hazard Model: The Example of Intentional Weight Loss and Mortality Rate.*  
Wang C, **Coffey CS**, Allison DB.  
**November 2004:** North American Association for the Study of Obesity Annual Scientific Meeting (Las Vegas, NV).
13. *Restructuring of Biostatistics at UAB.*  
Howard G, Beasley TM, **Coffey CS**, George V  
**August 2004:** Annual Joint Statistical Meetings (Toronto, ON).
12. *Genetic Programming Neural Network Has Improved Power in Comparison to Logistic Regression for Detecting Gene-Gene Interactions in Studies of Human Disease.*  
Ritchie MD, **Coffey CS**, Moore JH.  
**June 2004:** Annual Genetic and Evolutionary Computation Conference (Seattle, WA);  
Nominated for the Best Paper Award.

11. *Pharmacogenomics in Pulmonary Arterial Hypertension (PAH): The Relationship between an ET-1 Gene Polymorphism (PM) and Efficacy of Bosentan.*  
Benza RL, Mohanty GS, Grenett HE, **Coffey CS**, Rayburn BK, Tallaj JA, Law MA, Pinderski LJ, Pambokian SV, Bourge RC.  
**May 2004:** International Conference of the American Thoracic Society (Orlando, FL)
10. *Genotypes and Acute Chronic Rejection in Cardiac Transplant Recipients.*  
Benza RL, Barchue JP, Grenett HE, **Coffey CS**, Tallaj JA, Rayburn BK, Pinderski LJ, Pambokian SV, McGiffin DC, Kirklin JK, Bourge RC.  
**April 2004:** Annual Meeting and Scientific Sessions of the International Society for Heart and Lung Transplantation (San Francisco, CA)
9. *PAI-1 and Allograft Vasculopathy: Insights from a Murine Model of Transplantation.*  
Benza RL, Mohanty GS, **Coffey CS**, Anderson PG, Lyle K, George JF.  
**April 2004:** Annual Meeting and Scientific Sessions of the International Society for Heart and Lung Transplantation (San Francisco, CA)
8. *Caloric Restriction and Body Weight Independently Affect Longevity in Wistar Rats.*  
Wang C, Weindruch R, Fernandez JR, **Coffey CS**, Patel P, Allison DB.  
**November 2003:** North American Association for the Study of Obesity Annual Scientific Meeting (Ft. Lauderdale, FL).
7. *Fibrinolytic Proteins and Genotypes: Implications for Allograft Coronary Disease.*  
Benza RL, **Coffey CS**, Barchue JP, Cavender MA, Rayburn BK, Bourge RC, Tallaj JA, Kirklin JK, Pinderski LJ.  
**November 2003:** American Heart Association Annual Meeting (Orlando, FL).
6. *A Comparison of Data Mining and Logistic Regression Approaches for Detecting Gene-Gene Interactions.*  
Ritchie MD, **Coffey CS**, Moore JH.  
**November 2003:** Intl Genetic Epidemiology Society Meeting (Redondo Beach, CA)
5. *Adverse Effects of Beta Blocker Therapy for Heart Failure Patients: A Quantitative Overview.*  
Ko DT, Hebert PR, **Coffey CS**, Foody JM, Curtis JP, Sedrakyan A, Krumholz HM  
**November 2002:** American Heart Association Annual Meeting (Chicago, IL).
4. *Population Based Study of Methotrexate Use and Risk of Lymphoma in Patients with Rheumatoid Arthritis.*  
Watterson MK, Arrowsmith ER, **Coffey CS**, Cookson MS, Mitchel E, Stein CM  
**October 2002:** American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting (New Orleans, LA).
3. *Is There an Interaction between the ACE I/D and the PAI-1 4G/5G Gene Polymorphisms on Risk of Myocardial Infarction.*  
Hebert PR, **Coffey CS**, Ajani UA, Morgan TM, Brown NJ, Vaughan DE, Ridker PM.  
**November 2001:** American Heart Association Annual Meeting (Anaheim, CA).
2. *Amiodarone Delays Cellular Rejection in Bradycardic Transplant Patients.*  
Goldstein DR, Benza RL, Rayburn BK, Foley BA, **Coffey CS**, Thomas KL, Bourge. RC.  
**November 2001:** American Heart Association Annual Meeting (Anaheim, CA).
1. *Pathological Parameters in Radical Prostatectomies of Clinical Stage T1c versus T2 Prostate Carcinoma.*  
Jack GS, Vader V, **Coffey CS**, Cookson MS, Smith JA, Shappell SB  
**June 2001:** American Urological Association National Meeting (Anaheim, CA).

## GRANT ACTIVITY

### ACTIVE

***Network of Excellence in Neuroscience Clinical Trials (NEXT) – DCC*** [NIH U01 NS077352]  
10/01/2011-06/30/2023

The University of Iowa provides infrastructure to facilitate rapid development and implementation of protocols for conducting clinical trials in neuroscience. The infrastructure is designed to accommodate dynamically changing requirements that naturally occur in clinical trials (both planned and unplanned). The DCC will provide a more rapid evaluation of promising treatments in neuroscience, and be a model that can be replicated across several studies and diseases.

Role: PI, Data Coordinating Center

***Iowa Summer Institute for Research Education in Biostatistics*** [NIH R25 HL131467]  
02/15/16-02/28/2022

PI: G Zamba (U. Iowa)

The ultimate vision of the Summer Institute for Research Education in Biostatistics is to increase the number of undergraduates who enter graduate programs in biostatistics, and to maintain a solid underrepresented minority pipeline into biostatistics graduate programs. This project supports the University of Iowa, Department of Biostatistics in recruiting a diverse group of 18 trainees each year, from 2016 to 2018, with focus on minority, underrepresented, and disadvantaged students who may not have otherwise been exposed to the field of biostatistics.

Role: Co-Investigator

***A Randomized, Double-Blind, Placebo Controlled, Phase IIa, Parallel Group, Two-Cohort Study to Define the Safety, Tolerability, Clinical, and Exploratory Biological Activity of the Chronic Administration of Nilotinib in Patients with Parkinson's Disease – Biostatistics Coordinating Center***

T Simuni, PI (Northwestern)

03/01/2017 – 08/31/2020

The Biostatistics Coordinating Center provides statistical and clinical trial design support for the NILO PD study, and is responsible for all statistical analysis reports.

Role: PI, Biostatistics Coordinating Center

***MEDication Focused Outpatient Care for Underutilization of Secondary Prevention***  
[NIH R18 HL116259]

BL Carter, PI (U. Iowa)

04/01/2014 – 03/31/2020

The Data Coordinating Center will support the data collection, data management, clinical site support and monitoring, and statistical analyses for the MEDFOCUS study.

Role: PI, Data Coordinating Center

***The Parkinson's Progression Markers Initiative Statistical Core***

The Michael J. Fox Foundation for Parkinson's Research

06/24/2010-12/31/2019

The Parkinson's Progression Markers Initiative is a long-term study to follow 400 newly diagnosed patients with Parkinson's disease and 200 healthy controls over an extended period. One objective of the study is to investigate existing and novel clinical, imaging, and biomic Parkinson disease progression markers to identify quantitative individual measures or combinations of measures that demonstrate optimum interval change in PD patients compared to healthy controls, or in subsets of PD patients defined by baseline assessments.

Role: PI, Statistics Core

***Systemic Synuclein Sampling Study (S4) – Clinical, Data Management, & Statistical Core***

The Michael J. Fox Foundation for Parkinson's Research

03/01/2015 – 12/31/2019

The Clinical, Data Management, & Statistical Core will coordinate and oversee project clinical sites, develop and manage the project database housing clinical data, and perform clinical monitoring and quality

assurance and control for the multi-site project, develop project statistical analysis plans, and perform statistical analyses on project data.

Role: PI, Statistics Core

***Enhancing Scientific Inquiry in Clinical Neurosciences Through Methodology Training***

[U34 DK099845]

W Meurer, PI (U. Michigan)

04/01/2014 – 03/31/2020

As co-director of this course, Dr. Coffey's primary role is responsibility for the aspects of the educational plan related to biostatistics and data management. Additional responsibilities are to serve as a core faculty member and co-lead small groups as defined in the research education approach; and ensuring that the protocols developed within the training adhere to the standards of scientific rigor outlined in the NINDS guidelines.

Role: Subcontract PI; Course Co-Director

**ACTIVE NEURONEXT SUBCONTRACTS (NO FUNDED EFFORT – CTSDMC SUPPORT ONLY)**

***NN102 Sub award – Ibutilast in Phase II Trial in Progressive MS***

[U01 NS082329]

R Fox, PI (Cleveland Clinic)

07/15/2013 – 06/30/2020

Role: Subcontract PI

***NN106 Sub award – Cytochrome C Oxidase: Biomarker in Newly Diagnosed Glioblastoma Multiforme***

[U01 NS093663]

C Griguer, PI (University of Alabama at Birmingham)

09/30/2016 – 06/30/2020

Role: Subcontract PI

***NN107 Sub award – Effects of AFQ056 on Language Learning in Young Children with Fragile X Syndrome (FXS)***

[U01 NS096767]

E Berry-Kravis, PI (Rush)

09/30/2016 – 06/30/2020

Role: Subcontract PI

***NN108 Sub award – Topiramate as a Disease Altering Therapy for CSPN***

[U01 NS095388]

G Smith, PI (VCU)

07/01/2017 – 06/30/2021

Role: Subcontract PI

***NN109 Sub award – A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy of ManNAc in Subjects with GNE Myopathy***

[U01 AR070498]

A Amato, PI (MGH)

09/01/2017 – 04/30/2022

Role: Subcontract PI

**PREVIOUS**

**University of Iowa**

*Amyloid Imaging – PPMI Substudy*

The Michael J. Fox Foundation for Parkinson's Research

03/01/2014-02/28/2019

Role: PI, Statistics Core

*Three Site Assessment of the Potential for Home Dexterity Monitoring in a PD Biomarker Study (TAP-PD) – PPMI Sub Study*

The Michael J. Fox Foundation for Parkinson's Research

03/01/2014-02/28/2019

Role: PI, Statistics Core

*Amitriptyline and Topiramate in the Prevention of Childhood Migraine: DCC*

NIH U01 NS077108

09/30/2011-08/31/2017

Role: PI, Data Coordinating Center

*LRRK2 Cohort Consortium – Statistics*

The Michael J. Fox Foundation for Parkinson's Research

06/02/2011-11/30/2017

Role: PI, Statistics Core

*A Collaborative Model to Improve BP Control and Minimize Racial Disparities – DCC*

NIH R01 HL0918434

08/01/09 – 02/28/15

Role: PI, Data Coordinating Center

*Secondary Prevention of Small Subcortical Strokes SPS3)*

NIH U01 NS038529

OR Benavente, PI (University of British Columbia)

12/01/09 – 12/31/03

Role: Subcontract PI

*Adaptive Comparative Effectiveness Trials for Comparing Two Treatments*

UF11128

DR Nelson, PI (University of Florida)

05/23/11 – 03/31/12

Role: Subcontract PI

*Clinical Islet Transplantation: Data Coordinating Center (CIT: DCC)*

NIH U01 DK070431

WR Clarke, PI.

08/01/09 – 10/01/11

Role: Co-Investigator

*Carotid Occlusion Surgery Study (COSS): Data Management Center*

NIH U01 NS041985

WR Clarke, PI.

08/01/09 – 12/01/10

Role: Co-Investigator

NEURONEXT SUBCONTRACTS (NO FUNDED EFFORT – CTSDMC SUPPORT ONLY)

*NN101 Sub award – SMA Biomarkers in the Immediate Post-Natal Period of Development*

[U01 NS079163]

S Kolb, PI (The Ohio State University)

08/15/2012 – 07/31/2016

Role: Subcontract PI

*NN103 Sub award – A Phase II Trial of Rituximab in Myasthenia Gravis*

[U01 NS088312]

R Nowak, PI (Yale)

09/15/2013 – 07/31/2019

Role: Subcontract PI



*NN104 Sub award – ZZ3K3A-201: Safety Evaluation of 3K3A-APC in Ischemic Stroke*  
[U01 NS088312]  
P Lyden, PI (Cedars Sinai)  
07/01/2014 – 06/30/2018  
Role: Subcontract PI

*NN105 Sub award – Tolerability of SRX246 in Huntington's Disease Patients*  
[U44 NS090616]  
M Brownstein, PI (Azevan)  
09/01/2015 – 08/31/2018  
Role: Subcontract PI

### **University of Alabama at Birmingham**

*Merck Quantitative Science Fellowship Program*  
Merck  
08/22/07 – 07/31/09  
Role: PI

*Pharmacogenomics in Pulmonary Arterial Hypertension*  
NIH RO1 HL078946  
RL Benza, PI.  
09/01/05 – 07/31/09  
Role: Statistician

*Levels of Inflammatory Markers in the Treatment of Stroke*  
NIH RO1 NS050724  
MSV Elkind, PI (Columbia University).  
05/25/05 – 04/30/09  
Role: Subcontract PI

*Effects of Intentional Weight Loss on Mortality Rate*  
NIH RO1 DK067487  
DB Allison, PI.  
01/01/05 – 12/31/08  
Role: Co-Investigator

*Secondary Prevention of Small Subcortical Strokes*  
NIH UO1 NS038529  
OR Benavente, PI (UT Health Sciences Center at San Antonio).  
03/01/03 – 01/31/08  
Role: Subcontract PI

*Design and Analysis of Microarray Gene Expression Studies in Plants: Towards Sound Statistical Principles*  
NSF-01-158  
G Page, PI.  
01/01/03 – 12/31/07  
Role: Co-Investigator

*Internal Pilots for Repeated Measures ANOVA*  
NIH RO1 CA095749  
KE Muller, PI (University of North Carolina).  
01/15/03 – 12/31/07  
Role: Subcontract PI

*Genetic Variants and Thrombosis: Renin Angiotensin.*  
NIH RO1 HL99015  
PR Hebert, PI (Yale University).  
04/01/01 – 07/31/07  
Role: Subcontract PI

*Modulation of Innate Immunity in Lung Transplantation*  
NIH RO1 HL72871  
S. Matalon, PI.  
09/30/02 – 07/31/06  
Role: Statistician

*UT-15 Open Grant in Pulmonary Hypertension*  
United Therapeutics  
10/01/01 – 04/01/05  
Role: Statistician

## **STUDENTS MENTORED**

### **UNIVERSITY OF IOWA**

#### Chair (Doctoral Level):

3. Daniel Kang, Expected Graduation 2020.
2. Anne Wellhaven, Expected Graduation 2019.
1. Mitchell Thomann. “The Flexible Bivariate Continual Reassessment Method”, Graduated 2015.

#### Committee Member (Doctoral Level):

1. Janel Barnes. “Regression and Boosting Methods to Inform Precisionized Treatment Rules Using Data from Crossover Studies”, Graduated 2017.

#### Advisor (Preceptorship):

5. Elliot Burghardt. “Reproducibility of Living Data: Validation of Published Research Using the Parkinson’s Progression Marker Initiative Living Database”, Graduated 2019.
4. J. Tucker Krone. “Simulation Study Addressing Common Phase II Endpoint Selection Issues”, Graduated 2013.
3. Elizabeth Zahn. “A Survey on the Perception and Use of Adaptive Designs in Clinical Trials”, Graduated 2012.
2. Emily Lundt. “Prediction of the Implementation of the Physician-Pharmacist Collaborative Model Using the Theory of Planned Behavior”, Graduated 2011.
1. Chelsea Caspell. “Analysis of Parkinson’s Biomarker Candidates”, Graduated 2011.

### **UNIVERSITY OF ALABAMA AT BIRMINGHAM**

#### Chair (Doctoral Level):

3. William Prucka. “Wavelet-Based Regression and Classification for Longitudinal Diffusion Tensor Imaging Data”, Graduated 2008.
2. Nitin Nair. “Adaptive Procedures to Detect Treatment Effect Under Suspected Treatment-Covariate Interactions”, Graduated 2008.
1. David Sawrie. “Preemptive Power for the Consulting Statistician: Novel Applications of Internal Pilot Design and Information Based Monitoring Systems”, Graduated 2007.

Advisor (Masters Level):

5. Jiatao Ye (Co-Chair with Inmaculada Aban). "Power and Sample Size Estimation for a Three-Level Hierarchical Cluster Randomized Trial", Graduated 2010.
4. Kerri Howard. "Ambulatory Blood Pressure as Related to White Matter Hyperintensity: A Preemptive Power Approach", Graduated 2009.
3. John Bentley. "Cardiovascular Risk Associated with Polymorphisms in Genes from the Renin-Angiotensin, Bradykinin, and Fibrinolytic Systems", Graduated 2008.
2. Qing Li. "The Association of the Metabolic Syndrome with PAI-1 and t-PA Antigen Levels", Graduated 2005.
1. Lili Wang. "An Evaluation of a Two-Stage Procedure to Address Interactions in Two-Stage Designs", Graduated 2002.

Committee Member (Doctoral Level):

4. Samprit Banerjee. "Bayesian Genome-Wide QTL Mapping for Multiple Traits", Graduated 2008.
3. Qing Li. "Interim Monitoring Efficacy, Safety, and Futility in Phase III Clinical Trials", Graduated 2008.
2. Tamekia Jones. "A Statistical Approach Identifying and Limiting the Effect of Influential Observations in Linear Regression", Graduated 2007.
1. Ayanbola Ayanlowo. "Examination of Novel Statistical Designs for Phase II and Phase III Clinical Trials", Graduated 2007.

Committee Member (Master's Level):

4. Leigh Morton. "Comparison of Simon's Two-Stage Design, Sequential Probability Ratio Test, and Triangular Test in Phase II Clinical Trials", Graduated 2009.
3. Scott Marshall. "A Comparison of Procedures to Control Type I Error in Multiple Testing Situations: False Positive Report Probability (FPRP) vs. False Discovery Rate (FDR)", Graduated 2006.
2. Lang Chen. "Model Selection in Microarrays", Graduated 2004.
1. Dongyan Yang. "The Confounding of Race and Geography: How Much of the Excess Mortality among African Americans is Explained by Geography", Graduated 2002.

Committee Member (Other):

8. Christopher Snyder, MSPH. (Epidemiology) "The Relationship of Blood Product Ratio to Mortality: Survival Benefit or Survival Bias?", Graduated 2009.
7. Robert B. Hines, PhD. (Epidemiology) "Comorbidity and Body Mass Index (BMI) as Predictors of Survival for African-Americans and Caucasians Following Surgery for Adenocarcinoma of the Colon", Graduated 2009.
6. Madhav Bhatta, PhD. (Epidemiology) "Impact of Immunosuppression on the Incidence and Clearance of Human Pappillomavirus (HPV) in HIV-Infected Women in Alabama", Graduated 2007.
5. Hanzhu Qian, PhD. (Epidemiology) "Association of Plasma Donation with Human Immunodeficiency Virus and Hepatitis C Virus Infections in Rural Shanxi Province, China", Graduated 2005.
4. Christopher Krawczyk, PhD. (Epidemiology) "Factors Associated with Delayed Initiation of HIV Medical Care Among Infected Persons Attending an Urban HIV/AIDS Clinic", Graduated 2005.
3. Jonathon Bender, PhD. (Epidemiology) "Cancer Incidence Among Employees at Semiconductor and Storage Device Manufacturing Facilities", Graduated 2004.
2. Dominik Alexander, PhD. (Epidemiology) "Post-Surgical Disparity in Survival Between African-Americans and Caucasians with Colorectal Adenocarcinomas", Graduated 2004.

1. Akanid Wapeewutikorn, MS. (Epidemiology) "Use of Complementary and Alternative Medicine Among Cancer Patients and Menopausal Women in the U.S. General Population", Graduated 2003.

## **UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL**

### Chair (Doctoral Level):

1. John Kairalla (Co-Chair with Keith Muller). "An Internal Pilot Study with Interim Analysis for Gaussian Linear Models", Graduated 2007.

### Committee Member (Doctoral Level):

2. Sola Park. "Accounting for Bias and Uncertainty in Power for Multivariate Gaussian Linear Models", Graduated 2007
1. Michael Jiroutek (Dr. Ph). "Choosing a Sample Size for Estimating a Confidence Interval to Insure Good Properties", Graduated 2002.

## **HONORS AND AWARDS**

- 2018: University of Iowa College of Public Health Distinguished Faculty Lecture  
2016: University of Iowa College of Public Health Faculty Service Award  
2016: Named a Fellow of the American Statistical Association  
2015: Named a Fellow of the Society for Clinical Trials  
2013: University of Iowa College of Public Health Faculty Research Award  
2008: Science Unbound Foundation Award for Best Paper by a UAB Based Investigator in the Area of General Statistics  
2005: Grizzle Distinguished Alumni Award, UNC Department of Biostatistics  
2004: Science Unbound Foundation Award for Best Paper by a UAB Based Investigator in General Statistics  
2004: UAB President's Award for Excellence in Teaching - School of Public Health  
2003: Nomination for the Charles C. Shepard Science Award for most outstanding peer-reviewed paper published by CDC/ATSDR scientists during the preceding year (Prevention and Control Category)  
1999: Barry H. Margolin Dissertation Award, UNC Department of Biostatistics  
1995-1999: National Institute for Environmental Health Sciences Training Grant  
1997: Special Commendation, Theory Doctoral Exam, UNC Department of Biostatistics  
1997: Special Commendation, Applied Doctoral Exam, UNC Department of Biostatistics  
1997: Delta Omega Book Award, UNC School of Public Health  
1997: UNC School of Public Health Student Award  
1996: Inducted into Delta Omega Public Health Honor Society  
1993: Chancellor's Citation for Academic Excellence, University of Tennessee-Knoxville  
1992: Named "Top Graduate" in University of Tennessee College of Business Administration  
1992: Epsilon Eta Chapter of Sigma Nu Fraternity Scholar of the Year

## **OTHER PROFESSIONAL POSITIONS HELD**

### **UNIVERSITY OF NORTH CAROLINA DEPARTMENT OF BIOSTATISTICS (Chapel Hill, NC)**

1995-1999      Graduate Research Assistant

### **RHO, Inc. (Chapel Hill, NC)**

1998      Statistician II

### **COLLABORATIVE STUDIES COORDINATING CENTER (Chapel Hill, NC)**

1995      SAS Programmer

### **SCHLEGEL TENNESSEE, INC. (Maryville, TN)**

1993-1994      Advanced Quality Planning Engineer

### **SCHLEGEL, IOWA DIVISION (Keokuk, IA)**

1993      SPC Statistician

## PROFESSIONAL SERVICE

### GENERAL

**2019-Present:** Associate Editor – *Trials*

**2018-Present:** Member, FDA Gastrointestinal Drugs Advisory Committee

**2016-Present:** Associate Editor – *Clinical Trials*

**2011-Present:** Consulting Biostatistician – *Stroke*

**2007-Present:** Member, Drug Information Association (DIA - previously sponsored by PhRMA) Adaptive Designs Working Group

**2011-Present:** Member, DIA Adaptive Designs Working Group Case Studies Subteam

**2017:** External Reviewer, University of Rochester Experimental Therapeutics Fellows Program

**2011-2017:** Associate Editor – *Movement Disorders*

**2017:** Participant, The Michael J. Fox Foundation for Parkinson's Research Exenatide Trial Assessment Meeting

**2017:** Participant, The Michael J. Fox Foundation for Parkinson's Research Regulatory Workshop Planning Meeting – "Patient Selection & Stratification Biomarkers in Disease-Modifying Trials for Early-Stage PD"

**2016:** Member, ALS FDA Clinical Trials Guidelines Committee

**2007-2009:** Member, PhrMA Adaptive Designs Working Group Communications Workstream

### PROFESSIONAL ORGANIZATIONS

Society of Clinical Trials

**2016-Present:** Member, Communications Committee (Social Media Chair)

**2012-2017:** Board Member

**2012-2015:** Member, Program Committee

**2013-2014:** Program Chair

**2009-2012:** Chair, Education Committee

**2007-2012:** Member, Education Committee

**2009-2011:** Member, Education Outreach Committee

**2008-2009:** Co-Chair, Education Committee

American Statistical Association

**2011-2013:** Member, Biopharmaceutical Section Executive Committee

**2002-2009:** Chapter Representative for Alabama Chapter

**1999-2000:** Secretary for Middle Tennessee Chapter

Eastern North American Region (ENAR) of the International Biometric Society

**2007-2009:** Regional Advisory Board

**2007:** ENAR Program Chair for the Joint Statistical Meetings

Drug Information Association

American Academy of Neurology

### STUDY SECTIONS / GRANT REVIEWS

National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK)

**July 2019:** Reviewer ZDK1 GRB-9 (Clinical Centers)

**May 2019:** Reviewer, ZDK1 GRB-9 (Biostatistics Research Centers)

**March 2019:** Reviewer (Data Coordinating Center for Diabetic Foot Consortium)

Center for Scientific Review

**June 2019:** Reviewer, Acute Neural Injury & Epilepsy (ANIE) Study Section

Cure Parkinson's Trust

**May 2019:** Grant Reviewer

National Institute on Deafness and Other Communication Disorders (NIDCD)

**January 2019:** Reviewer, ZDC1 SRB-Y 54 (Clinical Trial Review)

**May 2018:** Reviewer, ZDC1 SRB-X 63 (NIDCD Aphasia Treatment Clinical Trial Review)

National Institute of Neurological Disorders and Stroke (NINDS)

**December 2018:** Reviewer, ZNS1 SRBA (Clinical Trial Readiness for Rare Neurological & Neuromuscular Diseases)

**December 2017:** Reviewer, ZNS-SRBA (Clinical Trial Readiness for Rare Neurological and Neuromuscular Diseases) Special Emphasis Panel

**July 2017:** Acting Chair, Reviewer, ZNS-1SRBA (Clinical Trial Readiness for Rare Neurological and Neuromuscular Diseases) Special Emphasis Panel

**December 2016:** Reviewer, ZNS1-SRBC (SIREN CCC) Special Emphasis Panel

**December 2016:** Reviewer, ZNS1-SRBC (SIREN DCC) Special Emphasis Panel

**March 2015:** Ad-Hoc Reviewer, ZNS1-SRBB Special Emphasis Panel

**August 2012:** Ad-Hoc Reviewer, ZNS1-SRBB Special Emphasis Panel

**March 2012:** Ad-Hoc Reviewer, NSD-K Study Section

**October 2011:** Ad-Hoc Reviewer, ZNS1-SRBS Special Emphasis Panel

**August 2011:** Ad-Hoc Reviewer, ZNS1-SRBS Special Emphasis Panel

**November 2010:** Ad-Hoc Reviewer, ZNS1-SRBB Special Emphasis Panel

**October 2010:** Ad-Hoc Reviewer, NSD-K Study Section

**June 2006-June 2010:** Member, NSD-K Study Section

**January 2010:** Ad-Hoc Reviewer, ZNS1-SRBB Special Emphasis Panel

**December 2009:** Ad-Hoc Reviewer, ZNS1-SRBB Special Emphasis Panel

**December 2008:** Ad-Hoc Reviewer, ZNS1-SRBB Special Emphasis Panel

**October 2005:** Ad-Hoc Reviewer, NSD-K Study Section

**June 2005:** Ad-Hoc Reviewer, NSD-A Study Section

**November 2004:** Ad-Hoc Reviewer, NSD-A Study Section

**February 2004:** Ad-Hoc Reviewer, NSD-A Study Section

**June 2003:** Ad-Hoc Reviewer, NSD-K Study Section

National Institute of Dental & Craniofacial Research (NIDCR)

**November 2018:** Chair, ZDE1 GZ08 (DPBRN Coordinating Center)

ALS Association

**March 2018:** Reviewer for Phase II Applications

**March 2016:** Reviewer for Phase II Applications

**December 2015:** Reviewer for Phase II Applications

**May 2015:** Reviewer for Phase II Applications

**February 2014:** Reviewer for Phase II Applications

**October 2013:** Reviewer for Phase II Applications

The Michael J. Fox Foundation for Parkinson's Research

**March 2019:** Reviewer for Biomarkers Across Neurodegenerative Diseases (BAND) Program

**October 2016:** Chair, PPMI Data Challenge Review

**October 2016:** Reviewer for Improved Biomarkers & Clinical Outcome Measures Program – Data Science Review

**August 2015:** Reviewer for Biomarkers across Neurodegenerative Diseases (BAND) Program

**August 2014:** Reviewer for Biomarkers across Neurodegenerative Diseases (BAND) Program

**January 2014:** Reviewer for Biomarker/Data Use Applications

**October 2011:** Reviewer for LRRK2 RFA Applications

National Center for Advancing Translational Sciences (NCATS) Therapeutics Discovery Study Section

**February 2013:** Ad-Hoc Reviewer

The Pacific Symposium on Biocomputing

**2004:** Reviewer

The Austrian Science Foundation Schroedinger Fellowship

**2002:** Reviewer

**2001:** Reviewer

## **DATA AND SAFETY MONITORING BOARDS**

**2018-Present:** Member, VA-Sponsored – “Microbiota or Placebo After Antimicrobial Therapy for Recurrent C. Difficile at Home (MATCH)” (CSP #2004)

**2017-Present:** Chair, NIH-Sponsored – Traumatic Injury Clinical Trial Evaluating Tranexamic Acid in Children (TIC-TOC): A Pilot and Feasibility Study

**2012-Present:** Member, NINDS-Sponsored – “Rapid Administration of Carnitine in Sepsis (RACE)” Trial

**2012-Present:** Member, National Institute of Aging (NIA) Sponsored – “Non-Invasive Treatment of Abdominal Aortic Aneurysm Clinical Trial (N-TA<sup>3</sup>CT)”

**2015-2018:** Member, DOD Sponsored – Chronic Effects of Neurotrauma Consortium (CENC)

**2005-2012:** Member, NINDS Sponsored - “Interventional Management of Stroke Study (IMS III) Trial”

**2005-2012:** Member, NINDS Sponsored - “Albumin in Acute Stroke (ALIAS)” Trial

**2009-2011:** Member, Medivation, Inc. Sponsored - “A Phase III, Randomized, Double-Blind, Placebo-Controlled Safety and Efficacy Study of Dimebon in Patients with Mild to Moderate Huntington’s Disease (HORIZON)”

**2008-2010:** Chair, NINDS Sponsored – “Chronic Migraine Treatment Trial”

**2008-2009:** Member, NINDS Sponsored - “Lithium in ALS (LALS) Trial”

**2008:** Member, National Center for Complementary and Alternative Medicine (NCCAM) Sponsored - “Creatine Safety Tolerability & Efficacy in Huntington’s Disease (CREST-E) Trial”

**2004-2008:** Member, NINDS Sponsored – “Clinical Trial of High Dose coQ10 in ALS (QALS) Trial”

**2003-2004:** Member, NINDS Sponsored - “Ankle Strengthening to Improve Gait and Function in CP Trial”

## **REFEREE MANUSCRIPTS**

Statistical Reviewer for:

*Stroke* (39 Total: 2003 - 4; 2004 - 2; 2005 - 5; 2006 – 2; 2007 – 3; 2008 – 1; 2009 – 1; 2010 – 3; 2011 – 5; 2012 – 6; 2013 – 1; 2014 – 3; 2017 – 1; 2018 – 1; 2019 - 1)

*Movement Disorders* (35 Total: 2010 – 4; 2011 – 11; 2012 – 4; 2013 – 6; 2014 – 3; 2015 – 4; 2016 – 3)

*Circulation* (6 Total: 2005 – 1; 2006 – 2; 2008 – 1; 2009 – 1; 2010 – 1)

Ad-Hoc Reviewer for Many Journals:

*Statistics in Medicine* (11 Total: 2000 - 1; 2003 - 1; 2004 - 1; 2005 – 1; 2006 – 3; 2011 – 1; 2012 - 1; 2013 – 1; 2014 – 1)

*Clinical Trials* (9 Total: 2008 -2; 2012 – 1; 2014 – 1; 2016 – 1; 2018 – 4)

*The Journal of the American Medical Association* (6 Total: 2004 - 1; 2005 – 1; 2007 - 1; 2013 - 3)

*Journal of Neurotrauma* (5 Total: 2004 – 3; 2005 – 2)

*Neurology* (5 Total: 2008 – 2; 2017 – 2; 2018 – 1)

*Obesity* (3 Total: 2010 – 1; 2011 – 1; 2017 – 1)

*Trials* (2 Total: 2014 – 1; 2015 – 1)

*Journal of Statistical Computation and Simulation* (2 Total: 2008 – 1; 2010 – 1)

*Epidemiology* (2 Total: 2007 – 1; 2008 - 1)

*The American Statistician* (2 Total: 2000 – 1; 2008 - 1)

*Hypertension* (2 Total: 2004 - 1; 2005 - 1)

*Biometrical Journal* (2 Total: 2009 – 1; 2012 - 1)  
*Journal of Biopharmaceutical Statistics* (1: 2019)  
*Journal of the Royal Statistical Society – Series A* (1: 2017)  
*The American Journal of Clinical Nutrition* (1: 2017)  
*Biometrics* (1: 2014)  
*International Journal of Biostatistics* (1: 2013)  
*Parkinsonism & Related Disorders* (1: 2012)  
*Pharmaceutical Statistics* (1: 2012)  
*Computer Methods and Programs in Biomedicine* (1: 2007)  
*Computational Statistics and Data Analysis* (1: 2005)  
*Behavior Research Methods, Instruments, & Computers* (1: 2004)  
*Applied Bioinformatics* (1: 2004)  
*Genetic Epidemiology* (1: 2004)  
*Neuroepidemiology* (1: 2004)  
*The American Journal of Human Genetics* (1: 2003)  
*Diabetes* (1: 2003)  
*Diabetologia* (1: 2003)  
*Obesity Reviews* (1: 2003)  
*Bioinformatics* (1: 2002)  
*Human Heredity* (1: 2002)  
*The Journal of the American Statistical Association* (1: 2002)

## **UNIVERSITY SERVICE**

### **UNIVERSITY OF IOWA**

**2016-Present:** University Conflict of Interest Review Committee

**2018:** Member, Search Committee for Stroke Division Director

### **UNIVERSITY OF ALABAMA AT BIRMINGHAM**

**2006-2009:** UAB Graduate Council

**2004-2008:** UAB Alternate Faculty Senator for School of Public Health

**2004-2008:** UAB Faculty Senate Curriculum and Research Committee

**2007:** Member, Committee to Select Recipient of the Ellen Gregg Ingalls/UAB National Alumni Society Award for Lifetime Achievement in Teaching

## **SCHOOL / COLLEGE OF PUBLIC HEALTH SERVICE**

### **UNIVERSITY OF IOWA**

**2011-2014:** College of Public Health Research Council

**2011:** College of Public Health Associate Dean Search Committee

**2009-2010:** Member, CEPH Accreditation Workshop 2.0 Committee

### **UNIVERSITY OF ALABAMA AT BIRMINGHAM**

**2008-2009:** Chair of the Faculty, UAB School of Public Health

**2008-2009:** School of Public Health Finance Committee

**2002-2009:** Contributor and Grader for Department of Epidemiology Written Examination

**2006-2007:** Member, Committee to Select Recipient of the President's Excellence in Teaching Award for the SoPH

**2006-2007:** Member, School of Public Health Associate Dean Search Committee

**2005:** Biostatistics representative to Department of Epidemiology PhD Review Committee

**2003-2005:** Chair, SoPH Admissions and Graduation Committee

**2002-2005:** SoPH Editorial Review Board

**2001-2005:** Dept. representative to SoPH Admissions and Graduation Committee



## **DEPARTMENT SERVICE**

### **UNIVERSITY OF IOWA**

**2016-Present:** Member, PhD Curriculum Review Committee

**2014-Present:** Chair, Woolson Award Selection Committee

**2018:** Co-Chair, Tenure Track Faculty Search Committee

**2017:** Member, Tenure Track Faculty Search Committee

**2015-2016:** Chair, Curriculum Committee

**2015:** Member, Department of Biostatistics DEO Search Committee

**2013:** Member, Doctoral Exam Restructuring Committee

**2012:** Chair, Clinical Track Faculty Search Committee

**2011:** Chair, Tenure Track Faculty Search Committee

**2009-2011:** MS Examinaton Committee

**2009-2011:** Admissions Committee

### **UNIVERSITY OF ALABAMA AT BIRMINGHAM**

**2006-2009:** Director of Graduate Studies

**2002-2009:** Graduate Program Committee

**2003-2006:** Dept. alternate representative to SPH Educational Policy Committee

**2005:** Interim Chair, Graduate Program Committee

**2001-2002:** Teaching Evaluation Committee

Member of several faculty search committees