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PERSONAL INFORMATION

Born: May 12, 1970, Kingsport, TN
Married, two sons

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
Statistical Methods for Clinical Trials (BIOS:6610)
Master's Level – Elective Course
Spring 2017: Course Instructor
Spring 2016: Course Instructor

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

Intervention and Clinical Trials (EPID:6900)

Doctoral Level – Epidemiology Course

Fall 2016: Presented lecture on “Adaptive Designs”

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”

Iowa Summer Institute of Biostatistics

Summer 2016: Presented lecture on “Overview of Randomized Clinical Trials & CTSDMC”

Summer 2015: Presented lecture on “Overview of Randomized Clinical Trials & CTSDMC”

Summer 2014: Presented lecture on “Overview of Randomized Clinical Trials”

Summer 2013: Presented lecture on “Overview of Randomized Clinical Trials”

Summer 2012: Presented lecture on “Overview of Randomized Clinical Trials”

Summer 2011: Presented lecture on “Overview of Randomized Clinical Trials”

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

Introduction to Translational Biomedicine (163:226)

Institute for Clinical & Translational Sciences (ICTS) Course

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

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

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 lecture – “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 2nd 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

19. *Clinical Trials in the Drug Development Pipeline*

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

18. *Clinical Trials Methods in Neurology*

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)

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

May 2015: Co-presenter with Daniele De Martini; Pre-conference workshop held in conjunction with the Annual Meeting of the Society for Clinical Trials (Montreal, QC)

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

April 2015: All day workshop as part of 8th 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

3. *Challenges in Designing Small Clinical Trials*
December 2011: Sponsored by the Association for Research in Vision and Ophthalmology (Webinar)
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

128. Amara AW, Chahine LM, Caspell-Garcia C, Long JD, **Coffey C**, Hognl 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*, in press.
127. 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 α -Synuclein Biomarker Studies in Biological Fluids: Peri-Analytical Considerations," *Movement Disorders*, in press.

126. 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.
125. Powers SW, **Coffey CS**, and Hershey AD (2017). "Treatment of Pediatric Migraine," *The New England Journal of Medicine*, 376(14): 1388-1389.
124. 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.
123. 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.
122. 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.
121. 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.
120. 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.
119. Lyden P, Weymer S, **Coffey C**, Cudkowicz M, Berg S, O'Brien S, Fisher M, Haley EC, Khatri P, Saver J, Levine S, Levy H, Rymer M, Wechsler L, Jadhav A, McNeil E, Waddy S, and Pryor K (2016). "Selecting Patients for Intra-Arterial Therapy in the Context of a Clinical Trial for Neuroprotection," *Stroke*, 47(12): 2979-2985.
118. Anderegg MD, Gums TH, Uribe L, **Coffey CS**, James PA, & Carter BL (2016). "Physician-Pharmacist Collaborative Management: Narrowing the Socioeconomic Blood Pressure Gap," *Hypertension*, 68(5): 1314-1320.
117. Fox RJ, **Coffey CS**, Cudkowicz ME, Gleason T, Goodman, A, Klawiter EC, Matsuda K, McGovern M, Conwit R, Naismith R, Ashokkumar A, Bermel R, Ecklund D, Koeppe M, Long J, Natarajan S, Ramachandran S, Skaramagas T, Thornell B, Yankey J, Agius M, Bashir K, Cohen B, Coyle P, Delgado S, Dewitt D, Flores A, Giesser B, Goldman M, Jubelt B, Lava N, Lynch S, Miravalle A, Moses H, Ontaneda D, Perumal J, Racke M, Repovic P, Riley C, Severson C, Shinnar S, Suski V, Weinstock-Gutman B, Yadav V, & Zabet A (2016). "Design, Rationale, and Baseline Characteristics of the Randomized Double-Blind Phase II Clinical Trial of Ibudilast in Progressive Multiple Sclerosis," *Contemporary Clinical Trials*, 50:166-177.
116. Simuni T, Long JD, Caspell-Garcia C, **Coffey CS**, Lasch S, Tanner CM, Jennings D, Kieburtz KD, & Marek K on behalf of the PPMI Investigators (2016). "Predictors of Time to Initiation of Symptomatic Therapy in Early Parkinson's Disease," *Annals of Clinical and Translational Neurology*, 3(7):482-494.
115. Simuni T, Caspell-Garcia C, **Coffey C**, Lasch S, Tanner C, & Marek K on behalf of the PPMI Investigators (2016). "How Stable are Parkinson's Disease Subtypes in De Novo Patients: Analysis of the PPMI Cohort," *Parkinsonism & Related Disorders*, 28:62-67.
114. McClure LA, Szychowski JM, Benavente O, Hart RG, & **Coffey CS** (2016). "A Post Hoc Evaluation of a Sample Size Re-Estimation in the Secondary Prevention of Small Subcortical Strokes Study," *Clinical Trials*, 13(5):537-544.

113. Marras C, Alcalay RN, Caspell-Garcia C, **Coffey C**, Chan P, Duda JE, Facheris MF, Fernandez-Santiago R, Ruiz-Martinez J, Mestre T, Saunders-Pullman R, Pont-Sunyer C, Tolosa E, & Waro B on behalf of the LRRK2 Cohort Consortium (2016). "Motor and Nonmotor Heterogeneity of LRRK2-Related and Idiopathic Parkinson's Disease," *Movement Disorders*, 31(8):1192-1202.
112. Powers SW, Hershey AD, **Coffey CS**, Chamberlin LA, Ecklund DJ, Sullivan SM, Klingner EA, Yankey JW, Kashikar-Zuck S, Korbee LL, Costigan ML, Riss HH, & Porter LL (2016). "The Childhood and Adolescent Migraine Prevention (CHAMP) Study: A Report on Baseline Characteristics of Participants," *Headache*, 56(5): 859-870.
111. Polgreen LA, Han J, Carter BL, Ardery GP, **Coffey CS**, Chrischilles EA, & James PA (2015). "Cost-Effectiveness of a Physician-Pharmacist Collaboration Intervention to Improve Blood Pressure Control," *Hypertension*, 66(6): 1145-1151.
110. Kang JH, Mollenhauer B, **Coffey CS**, Toledo JB, Weintraub D, Galasko DR, Irwin DJ, Van Deerlin V, Chen-Plotkin AS, Caspell-Garcia C, Waligorska T, Taylor P, Shah N, Pan S, Zero P, Frasier M, Marek K, Keiburtz K, Jennings D, Tanner CM, Simuni T, Singleton A, Toga AW, Chowdhury S, Trojanowski JQ, & Shaw LM on behalf of the Parkinson's Progression Markers Initiative (2016). "CSF Biomarkers Associated with Disease Heterogeneity in Early Parkinson's Disease: The Parkinson's Progression Marker's Initiative Study," *Acta Neuropathologica*, 131(6): 935-949.
109. Smith SM, Carris NW, Dietrich E, Gums JG, Uribe L, **Coffey C**, Gums TH, & Carter BL (2016). "Physician-Pharmacist Collaboration versus Usual Care for Treatment-Resistant Hypertension," *Journal of the American Society for Hypertension*, 10(4): 307-317.
108. Kolb SJ, **Coffey CS**, Yankey JW, Krosschell K, Arnold WD, Rutkove SB, Swoboda KJ, Reyna SP, Sankoku A, Darras BT, Shell R, Kuntz N, Castro D, Iannaccone ST, Parsons J, Connolly AM, Chiriboga CA, McDonald C, Burnette WB, Werner K, Thangarajh M, Shieh PB, Finanger E, Cudkowicz ME, McGovern MM, McNeil DE, Finkel R, Kaye E, Kingsley A, Renusch SR, McGovern VL, Wang X, Zaworkski PG, Prior TW, Burghes AHM, Bartlett A, Kissell JT & the NeuroNEXT Clinical Trial Network on behalf of the NN101 SMA Biomarker Investigators (2016). "Baseline Results of the NeuroNEXT Spinal Muscular Atrophy Infant Biomarker Study," *Annals of Clinical and Translational Neurology*, 3(2): 132-145.
107. Schuff N, Wu IW, Foster ED, **Coffey CS**, Gitelman DR, Mendick S, Seibyl J, Simuni T, Zhang Y, Jankovic J, Hunter C, Tanner CM, Rees L, Factor S, Berg D, Wurster I, Gauss K, Sprenger F, Seppi K, Poewe W, Mollenhauer B, Knake S, Mari Z, McCoy A, Rowe D, Ranola M, and Marek K (2015). "Diffusion Imaging of Nigral Alterations in Early Parkinson's Disease with Dopaminergic Deficits," *Movement Disorders*, 30(14): 1885-1892.
106. Powers WJ, Derdeyn CP, Biller J, **Coffey CS**, Hoh BL, Jauch EC, Johnston KC, Johnston SC, Khalessi AA, Kidwell CS, Meschia JF, Ovbiagele B, and Yavagal DR on Behalf of the American Heart Association Stroke Council (2015). "2015 American Heart Association/American Stroke Association Focused Update of the 2013 Guidelines for the Early Management of Patients with Acute Ischemic Stroke Regarding Endovascular Treatment: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association," *Stroke*, 46(10): 3020-3035.
105. Carter BL, **Coffey CS**, Chrischilles EA, Ardery G, Ecklund D, Gryzlak B, Vander Weg MW, James PA, Christensen AJ, Parker CP, Gums T, Finkelstein RJ, Uribe L, and Polgreen LA on behalf of the MEDication Focused Outpatient Care for Underutilization of Secondary Prevention (MEDFOCUS) Trial Investigators (2015). "A Cluster-Randomized Trial of a Centralized Clinical Pharmacy Cardiovascular Risk Service to Improve Guideline Adherence," *Pharmacotherapy*, 35(7): 653-662.
104. Simuni T, Caspell-Garcia C, **Coffey C**, Chahine LM, Lasch S, Oertel WH, Mayer G, Hogg B, Postuma R, Videnovic A, Amara AW, and Marek K for the PPMI Sleep Working Group on Behalf of the PPMI Investigators (2015). "Correlates of Excessive Daytime Sleepiness in De Novo Parkinson's Disease: A Case Control Study," *Movement Disorders*, 30(10): 1371-1381.
103. Gums TH, Uribe L, Vander Weg MW, James P, **Coffey C**, and Carter BL (2015). "Pharmacist Intervention for Blood Pressure Control: Medication Intensification and Adherence," *Journal of the American Society for Hypertension*, 9(7): 569-578.

102. Zhang Y, Wu IW, Buckley S, **Coffey CS**, Foster E, Mendick S, Seibyl J, and Schuff N (2015). "Diffusion Tensor Imaging of the Nigrostriatal Fibers in Parkinson's Disease," *Movement Disorders*, 30(9): 1229-1236.
101. Carter BL, **Coffey CS**, Ardery G, Uribe L, Ecklund D, James P, Egan B, Vander Weg M, Chrischilles E, and Vaughn T (2015). "A Cluster-Randomized Trial of a Physician/Pharmacist Collaborative Model to Improve Blood Pressure Control," *Circulation: Cardiovascular Quality & Outcomes*, 8(3): 235-243.
100. Weintraub D, Simuni T, Caspell-Garcia C, **Coffey C**, Lasch S, Siderowf A, Aarsland D, Barone P, Burn D, Chahine LM, Eberling J, Espay AJ, Foster ED, Leverenz JB, Litvan I, Richard I, Troyer MD, Hawkins, KA, and the Parkinson's Progression Markers Initiative (2015). "Cognitive Performance and Neuropsychiatric Symptoms in Early, Untreated Parkinson Disease," *Movement Disorders*, 30(7): 919-927.
99. **Coffey CS** (2015). "You May Have Worked on More Adaptive Designs than You Think," *Stroke*, 46(2): e26-28.
98. Lau H, White CL, **Coffey C**, Kase CS, Babikian VL et al. (2015). "Clinical Trial Participation and Health Behavior Modification: Secondary Prevention of Small Subcortical Strokes (SPS3)," *J Neurol Disord Stroke*, 3(1): 1094.
97. Kairalla JA, **Coffey CS**, Thomann MA, Shorr RI, and Muller KE (2015). "Adaptive Designs for Comparative Effectiveness Research Trials," *Clinical Research and Regulatory Affairs*, 32(1): 36-44.
96. Sharma M, Pearce LA, Benavente OR, Anderson DC, Connolly SJ, Palacio S, **Coffey CS**, and Hart RG (2014). "Predictors of Mortality in Patients with Lacunar Stroke in the Secondary Prevention of Small Subcortical Strokes Trial," *Stroke*, 45(10): 2989-2994.
95. Gums TH, Carter BL, Milavetz G, Buys L, Rosenkrans K, Uribe L, Coffey C, MacLaughlin EJ, Young RB, Ables AZ, Patel-Shori N, and Wisniewski A (2014). "Physician-Pharmacist Collaborative Management of Asthma in Primary Care," *Pharmacotherapy*, 34(10): 1033-1042.
94. Yeatts SD, Martin RH, **Coffey CS**, Lyden PD, Foster LD, Woolson RF, Broderick JP, and Palesch YY (2014). "The Challenges of Decision Making Regarding Futility in a Randomized Trial: The IMS-III Experience," *Stroke*, 45(5): 1408-1414.
93. Morgan C, Huyck S, Jenkins M, Chen L, Bedding A, **Coffey C**, Gaydos B, and Wathen J (2014). "Adaptive Design: Results of 2012 Survey on Perception and Use," *Therapeutic Innovation & Regulatory Science*, 48(4): 473-481.
92. Elkind MS, Luna JM, McClure LA, Zhang Y, **Coffey CS**, Roldan A, Del Brutto O, Pretell EJ, Pettigrew LC, Meyer BC, Tapia J, White C, and Benavente OR on behalf of the LIMITS Investigators (2014). "C-Reactive Protein as a Prognostic Marker After Lacunar Stroke: Levels of Inflammatory Markers in the Treatment of Stroke Study," *Stroke*, 45(3): 707-716.
91. Galpern WR, **Coffey CS**, Albanese A, Cheung K, Comella CL, Ecklund DJ, Fahn S, Jankovic J, Kiebertz K, Lang AE, McDermott MP, Shefner JM, Teller JK, Thompson JLP, Yeatts SD, and Jinnah HA (2014). "Designing Clinical Trials for Dystonia," *Neurotherapeutics*, 11(1): 117-127.
90. Kang JH, Irwin DJ, Chen-Plotkin AS, Siderowf A, Caspell C, **Coffey CS**, Waligorska T, Taylor P, Pan S, Frasier M, Marek K, Kiebertz K, Jennings D, Simuni T, Tanner CM, Singleton A, Toga AW, Chowdhury S, Mollenhauer B, Trojanowski JQ, Shaw LM and the Parkinson's Progression Marker Initiative Investigators (2013). "Association of Cerebrospinal Fluid A β ₁₋₄₂, t-tau, p-tau₁₈₁, and α -synuclein Levels with Clinical Features of Early Drug Naïve Parkinson's Disease Patients," *Archives of Neurology*, 70(10): 1277-1287.
89. Leira EC, **Coffey CS**, Jorge RE, Morton SM, Froehler MT, Davis PH, and Adams HP (2013). "The NIHSS Supplementary Motor Scale: A Valid Tool for Multidisciplinary Recovery Trials," *Cerebrovasc Dis*, 36(1): 69-73.
88. The SPS3 Investigators (2013). "Effects of Blood Pressure Targets in Patients with Recent Lacunar Stroke," *Lancet*, 382(9891): 507-515. (Writing Group: Benavente OR, **Coffey CS**, Conwit R, Hart RG, McClure LA, Pearce LA, Pergola PE, and Szychowski JM)

87. DeMik DE, VanderWeg WM, Lundt ES, **Coffey CS**, Ardery G, and Carter BL (2013). "Using Theory to Predict Implementation of a Physician-Pharmacist Collaborative Intervention within a Practice-Based Research Network," *Research in Social and Administrative Pharmacy*, 9(6): 719-730.
86. Leira EC, Jorge RE, **Coffey CS**, Morton SM, Froehler MT, Davis PH, and Adams HP (2013). "The NIHSS Supplementary Motor Scale: A Valid Tool for Multidisciplinary Recovery Trials," *Cerebrovas Dis*, 36: 69-73.
85. White CL, Szychowski JM, Roldan A, Benavente MF, Pretell EJ, Del Brutto OH, Kase CS, Arauz A, Meyer BC, Meissner I, Demaerschalk BM, McClure LA, **Coffey CS**, Pearce LA, Conwit R, Irby LH, Peri K, Pergola PE, Hart RG, and Benavente OR for the SPS3 Investigators. "Clinical Features and Racial/Ethnic Differences among the 3020 Participants in the Secondary Prevention of Small Subcortical Strokes (SPS3) Trial," *Journal of Stroke and Cerebrovascular Diseases*, 22(6): 764-774.
84. Carter BL, **Coffey CS**, Uribe L, James PA, Egan BM, Ardery G, Chrischilles EA, Ecklund D, VanderWeg M, and Vaughn T on behalf of the Collaboration Among Pharmacists and Physicians to Improve Outcomes Now (CAPTION) Trial Investigators (2013). "Similar Blood Pressure Values Across Racial and Economic Groups: Baseline Data from a Group Randomized Trial," *The Journal of Clinical Hypertension*, 15(6): 404-412.
83. Hershey AD, Powers SW, **Coffey CS**, Ecklund D, Chamberlin LA, and Korbee LL on behalf of the CHAMP Study Group (2013). "Childhood and Adolescent Migraine Prevention (CHAMP) Study: A Double-Blinded, Placebo-Controlled, Comparative Effectiveness Study of Amitriptyline, Topiramate, and Placebo in the Prevention of Childhood and Adolescent Migraine," *Headache*, 53(5): 799-816.
82. McClure LA, **Coffey CS**, and Howard GH (2013). "Monitoring Futility in a Two-by-Two Factorial Design: The SPS3 Experience," *Clinical Trials*, 10(2): 250-256.
81. **Coffey CS**, Levin B, Clark C, Timmerman C, Wittes J, Gilbert P, and Harris S (2012). "Overview, Hurdles, and Future Work in Adaptive Designs: Perspectives from a National Institutes of Health-Funded Workshop," *Clinical Trials*, 9(6): 671-680.
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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." In Ravina B, Cummings MP, McDermott MP, and Poole M (Ed.), *Clinical Trials in Neurology*. Cambridge University Press.
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*, in press.
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].

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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

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 8th 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 2017: 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: 8th 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, The 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, The 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: 4th Annual SPS3 Investigator's Meeting (San Antonio, TX)
11. *Premature Termination of Clinical Trials*
September 2005: 3rd 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)

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, Kieburtz 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, Kieburtz 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, Renusch 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: Annual Meeting of the Society for Clinical Trials (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: Annual Meeting of the Society for Clinical Trials (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: Annual Meeting of the Society for Clinical Trials (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: 18th 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: 18th 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: 18th 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: 18th 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: 18th 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: Annual Meeting of the Society for Clinical Trials (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: Annual Meeting of the Society for Clinical Trials (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: Annual Meeting of the Society for Clinical Trials (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: Annual Meeting of the Society for Clinical Trials (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, Logsdon-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: Annual Meeting of the Society for Clinical Trials (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: Annual Meeting of the Society for Clinical Trials (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: Annual Meeting of the Society for Clinical Trials (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: Annual Meeting of the Society for Clinical Trials (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: Annual Meeting of the Society for Clinical Trials (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.
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: Annual Meeting of the Society for Clinical Trials (Atlanta, GA)
57. *Monitoring Futility in Two-by-Two Factorial Studies*. McClure LA, Howard G, and **Coffey CS**.
May 2009: Annual Meeting of the Society of Clinical Trials (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: Annual Meeting of the Society of Clinical Trials (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 McGoan 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: Annual Meeting of the Society for Clinical Trials (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: 21st International 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: 21st International 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**: 21st International 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

Enhancing Scientific Inquiry in Clinical Neurosciences Through Methodology Training

[U34 DK099845]

W Meurer, PI (U. Michigan)

04/01/2014 – 03/31/2019

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

MEDication Focused Outpatient Care for Underutilization of Secondary Prevention

[NIH R18 HL116259]

BL Carter, PI (U. Iowa)

04/01/2014 – 03/31/2019

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

Amyloid Imaging – PPMI Sub study

The Michael J. Fox Foundation for Parkinson's Research

03/01/2014-02/28/2019

A sub-study focused on integrating amyloid imaging into PPMI. The DCC is responsible for analysis of collected amyloid imaging data.

Role: PI, Statistics Core

Iowa Summer Institute for Research Education in Biostatistics [NIH R25 HL131467]

02/15/16-01/31/19

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

The Parkinson's Progression Markers Initiative Statistical Core

The Michael J. Fox Foundation for Parkinson's Research

06/24/2010-12/31/2018

The Michael J. Fox Foundation is currently planning a long-term study to follow 400 newly diagnosed patients with Parkinson's disease and 200 healthy controls over a period of 3-5 years. 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

Network of Excellence in Neuroscience Clinical Trials (NEXT) – DCC [NIH U01 NS077352]

09/30/2011-06/30/2018

The University of Iowa will provide 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 a number of studies and diseases.

Role: PI, Data Coordinating Center

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

The Michael J. Fox Foundation for Parkinson's Research

03/01/2015 – 02/28/2018

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

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 – 02/28/2018

An ancillary project to the Parkinson's Progression Markers Initiative Statistics Core, focused on assessing an objective measurement device among individuals with risk factors for Parkinson's disease.

Role: PI, Statistics Core

Amitriptyline and Topiramate in the Prevention of Childhood Migraine: DCC [NIH U01 NS077108]

09/30/2011-08/31/2017

The University of Iowa will develop and support a web-based distributed data entry system with the capability to quickly, efficiently, and accurately randomize subjects and collect data generated by the clinical trial; provide project management support for the trial; support trial-wide safety monitoring; and provide study design and statistical leadership for the trial.

Role: PI, Data Coordinating Center

LRRK2 Cohort Consortium – Statistics

The Michael J. Fox Foundation for Parkinson's Research

06/02/2011-06/30/2017

The statistics team of LRRK2 conducts ongoing analysis of centralized database information and performs data integrity checks; advises and participates in project working groups; develops statistical recommendations for the project; and performs statistical analyses on collected project data.

Role: PI, Statistics Core

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

NN102 Sub award – Ibudilast in Phase II Trial in Progressive MS

[U01 NS082329]

R Fox, PI (The Cleveland Clinic)

07/15/2013 – 06/30/2018

Role: Subcontract PI

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

[U01 NS088312]

R Nowak, PI (Yale)

09/15/2013 – 07/31/2017

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

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

PREVIOUS

University of Iowa

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

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):

1. Mitchell Thomann. "The Flexible Bivariate Continual Reassessment Method", Graduated 2015.
2. Anne Wellhaven. Expected Graduation 2018.

Committee Member (Doctoral Level):

1. Janel Barnes, Expected Graduation 2017.

Advisor (Preceptorship):

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", 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

- 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 the Area of 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

2016-Present: Associate Editor – *Clinical Trials*

2011-Present: Consulting Biostatistician – *Stroke*

2011-Present: 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-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

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

PROFESSIONAL ORGANIZATIONS

Society of Clinical Trials

2016-Present: Chair, Social Media Committee

2012-Present: Board Member

2013-2014: Program Chair

2012-2015: Member, Program Committee

2009-2012: Chair, Education Committee

2007-2012: Member, Education Committee

2009-2011: Member, Education Outreach Committee

2008-2009: Co-Chair, Education Committee

2007-2009: Organizer, Fundamentals of Clinical Trials Workshop

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

STUDY SECTIONS / GRANT REVIEWS

National Institute of Neurological Disorders and Stroke (NINDS)

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

The Michael J. Fox Foundation for Parkinson's Research

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

ALS Association

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

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

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

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

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-TA³CT)”

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 (36 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)

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)

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)

Clinical Trials (5 Total: 2008 - 2; 2012 - 1; 2014 - 1; 2016 - 1)

Trials (2 Total: 2014 - 1; 2015 - 1)

Obesity (2 Total: 2010 - 1; 2011 - 1)

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

Neurology (2: 2008)

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)

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

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

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

Member of several faculty search committees

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