

BIOGRAPHICAL SKETCH

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Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Christopher S. Coffey

eRA COMMONS USER NAME (credential, e.g., agency login): ccoffey

POSITION TITLE: Professor

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Tennessee, Knoxville, TN	B.S.	12/92	Statistics
University of North Carolina, Chapel Hill, NC	M.S.	12/96	Biostatistics
University of North Carolina, Chapel Hill, NC	Ph.D.	12/99	Biostatistics

A. Personal Statement

B. Positions and Honors

Positions and Employment

06/98-08/98	Statistician, RHO, Inc., Chapel Hill, NC
07/95-07/99	Graduate Research Assistant, Univ. of North Carolina Dept. of Biostatistics, Chapel Hill, NC
08/99-01/01	Assistant Professor of Biostatistics, Vanderbilt University School of Medicine, Nashville, TN
02/01-09/04	Assistant Professor of Biostatistics, University of Alabama at Birmingham, Birmingham, AL
10/04-07/09	Associate Professor of Biostatistics, University of Alabama at Birmingham, Birmingham, AL
10/06-07/09	Director of Graduate Studies, Department of Biostatistics, University of Alabama at Birmingham
08/09-Present	Professor of Biostatistics, University of Iowa, Iowa City, IA
08/09-08/10	Deputy Director, Clinical Trials Statistical and Data Management Center (CTSDMC), The University of Iowa
08/10-Present	Director, CTSDMC, The University of Iowa

Other Experience and Professional Memberships

1999 – Present	Member, American Statistical Association (Named Fellow – 2016)
2007 – Present	Member, Society for Clinical Trials (Named Fellow – 2015)

Honors

1997	UNC School of Public Health Student Award
1999	Barry H. Margolin Dissertation Award, UNC Department of Biostatistics
2004	UAB President’s Excellence in Teaching Award for the School of Public Health
2004, 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
2013	University of Iowa College of Public Health Faculty Research Award
2016	University of Iowa College of Public Health Faculty Service Award

C. Contributions to Science

A biostatistician may have an impact through changing practice in a “retail” manner by direct collaboration in important studies or in a “wholesale” manner by publishing methodology used in many studies. Despite the administrative responsibilities of leading the CTSDMC, I am very proud of the fact that my publication record has remained consistent since taking over as the Director of the CTSDMC. In general, my contributions to science can be categorized into three general categories:

- **Methodology & Utilization of Adaptive Designs**

Throughout my career, I have maintained an interest in adaptive clinical trial designs. This interest has led to a number of important publications, a few of which are listed below:

Coffey CS (2015). "You May Have Worked on More Adaptive Designs than You Think," *Stroke*, 46(2): e26-28.

Kairalla JA, **Coffey CS**, Thomann MA, and Muller KE (2012). "Adaptive Trial Designs: A Review of Barriers and Opportunities," *Trials*, Aug 23; 13: 145. PMID: 22917111, PMCID: PMC2519822

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.

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. PMID: 23250942

As a result of these publications, I have established myself as a leader in the area of adaptive clinical trials. I currently serve on the Drug Information Association Adaptive Design Scientific Working Group, a group combining individuals from industry and academic to make recommendations to FDA and other regulatory bodies addressing concerns and encouraging the proper use of adaptive designs. I have also been regularly invited to give invited presentations and teach short courses on the topic. For example, during Fall 2017 I will be giving several short courses on adaptive designs across the country as part of the American Statistical Association Traveling Course series.

- **Overseeing the Conduct of Multi-Site Clinical Trials**

Since I was brought to Iowa to ensure the continued success of the CTSDMC, I have been very active with regards to obtaining funding for new projects in the Center. Currently, the projects in the CTSDMC collectively bring in over \$5 million dollars annually in direct costs and support 3.0 faculty and 36.0 staff FTE's. As a result of these efforts, the CTSDMC has become a leader in the field of clinical trials, particularly in the neurosciences. In 2011, we competed with many other groups nationally and were awarded the Data Coordinating Center for the NINDS-funded Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT). As a result of these efforts, the results of studies I have been involved with have been published in a number of high profile journals. A few examples are cited below:

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.

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*, in press. PMID: 20647575 PMCID: PMC2931811

The SPS3 Investigators (Writing Group: Benavente OR, McClure LA, **Coffey CS**, Szychowski JM, Pearce LA, and Hart RG) (2012). "Effects of Clopidogrel Added to Aspirin in Patients with Recent Lacunar Stroke," *New England Journal of Medicine*, 367(9): 817-825. PMID: 22931315

Clifton GL, Valadka A, Zygun D, **Coffey CS**, Drever P, Fourwinds S, Janis LS, Wilde E, Taylor P, Harshman K, Conley A, Puccio A, Levin HS, McCauley SR, Bucholz RD, Smith KR, Schmidt JH, Scott JN, Yonas H, and Okonkwo D (2011). "Very Early Hypothermia Induction in Patients with Severe Brain Injury (National Acute Brain Injury Study: Hypothermia II): A Randomized Trial," *Lancet Neurology*, 10(2): 131-139.

- **Providing Statistical Expertise to Research in the Neurosciences**

Throughout my career, I have been involved in a number of projects that span many different areas in the neurosciences. In doing so, I have become well positioned as one of the few statisticians working on multiple studies in the neurosciences. This experience helped position me well to lead complex projects like NeuroNEXT, as well as serving as a Co-PI on the recently NINDS-funded Clinical Trials Methods training course. In addition to the manuscripts cited above, a few additional examples of my major contributions to the neuroscience literature are cited below:

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.

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.

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 AHA/ASA Focused Update of the 2013 Guidelines for the Early Management of Patients With Acute Ischemic Stroke Regarding Endovascular Treatment," *Stroke*, 46(10): 3020-3035.

Galpern WR, **Coffey CS**, Albanese A, Cheung K, Comella CL, Ecklund DJ, Fahn S, Jankovic J, Kieburtz 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.

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

The Michael J. Fox Foundation for Parkinson's Research 06/24/2010 – 05/31/2019

The Parkinson's Progression Markers Initiative Statistical Core

The Michael J. Fox Foundation is conducting 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: Head of Statistical Core

NIH U01 NS077352 09/30/2011 – 06/30/2023

Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT) – DCC

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.

The NeuroNEXT infrastructure also supports the Clinical Trials Methodology Course. Dr. Coffey's primary role as a co-program director of the course 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. Course management comprises 1.2 calendar months of this effort.

Role: PI, Data Coordinating Center

NIH R18 HL116259 (PI: Carter) 04/01/2014 – 03/31/2020

MEDication Focused Outpatient Care for Underutilization of Secondary Prevention

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

Role: PI, Data Coordinating Center

University of Michigan 3003150719 (PI: Meurer) 04/01/2014 – 03/31/2019

Enhancing Scientific Inquiry in Clinical Neurosciences Through Methodology Training

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: Contact PI; Course Co-Director

The Michael J. Fox Foundation for Parkinson's Research 05/27/2015 – 02/28/2019

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

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

The Michael J. Fox Foundation for Parkinson's Research 03/01/2017 – 08/31/2020

Nilotinib in Parkinson's Disease Study – Biostatistics Coordinating Center

The Statistics Team at the BCC is responsible for assisting with protocol development, developing a statistical analysis plan, producing key weekly/monthly/quarterly/safety/DSMB reports for the study, performing all data analysis for the

study, and assisting with manuscript preparation and dissemination of final study results.

Role: PI, Biostatistics Coordinating Center

NIH R25 HL147231 (PI: Zamba)

03/01/2019 – 02/28/2022

Iowa Summer Institute for Research Education in Biostatistics (ISIREB)

This is a proposal to the National Institutes of Health (NIH), National Heart, Lung and Blood Institute (NHLBI), from the University of Iowa, in response to RFA-HL-19-019 for an Iowa Summer Institute for Research Education in Biostatistics (ISIREB), Summer Programs 2019, 2020, & 2021.

Role: Co-Investigator

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

NIH U01 NS093663 (PI: Griguer, UAB)

09/30/2016 – 06/30/2020

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

Role: Subcontract PI

NIH U01 NS096767 (PI: Berry-Kravis, Rush)

09/30/2016 – 06/30/2020

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

Role: Subcontract PI

NIH U01 NS095388

07/01/2017 – 06/30/2021

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

Role: Subcontract PI

Completed Research Support (Past 3 Years)

NIH U01 NS077108

09/30/2011 – 08/31/2017

Amitriptyline and Topiramate in the Prevention of Childhood Migraine: DCC

Role: PI, Data Coordinating Center

The Michael J. Fox Foundation For Parkinson's Research

09/30/2011 – 06/30/2017

LRRK2 Cohort Consortium – Statistics

Role: PI, Statistics Core

NIH R01 HL0918434

08/01/2009 – 02/28/2015

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

Role: PI, Data Coordinating Center

NIH R25 HL131467 (PI: Zamba)

02/15/2016 – 01/31/2019

Iowa Summer Institute for Research Education in Biostatistics

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

NEURONEXT SUBCONTRACTS (NO FUNDED EFFORT – CTSDMC SUPPORT ONLY)

NIH U01 NS079163 (PI: Kolb, Ohio State)

08/15/2012 – 07/31/2016

NN101 Sub award – Ibudilast in Phase II Trial in Progressive MS

Role: Subcontract PI

NIH U01 NS082329 (PI: Fox, Cleveland Clinic)

07/15/2013 – 06/30/2018

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

Role: Subcontract PI

NIH U01 NS088212 (PI: Nowak, Yale)

09/15/2013 – 07/31/2018

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

Role: Subcontract PI

NIH U01 NS088312 (PI: Lyden, Cedars Sinai)

07/01/2014 – 06/30/2018

NN104 Sub award – ZZ3K3A-201: Safety Evaluation of 3K3A-APC in Ischemic Stroke

Role: Subcontract PI

NIH U01 NS090616 (PI: Brownstein, Azevan)

09/01/2015 – 08/31/2018

NN105 Sub award – Tolerability of SRX246 in Huntington's Disease Patients

Role: Subcontract PI