BIOGRAPHICAL SKETCH

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NAME	POSITION TITLE
Christopher S. Coffey	Professor
eRA COMMONS USER NAME ccoffey	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	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

I joined the faculty at the University of Iowa in fall 2009 as a Professor in the Department of Biostatistics and became the Director of the Clinical Trials Statistical and Data Management Center (CTSDMC) in August 2010. I received my Ph.D. in biostatistics from the University of North Carolina at Chapel Hill in 1999 and have over ten years of experience providing data management and statistical support to large randomized clinical trials. I have also served as the primary statistician for multi-site clinical trials in stroke, obesity, traumatic brain injury, headache, and hypertension. I am also a past member of the NINDS NSD-K clinical trials study section, currently serve on a number of Data and Safety Monitoring Boards, chair the education committee of the Society for Clinical Trials, and have participated in each of the past four years as a faculty member in the NINDS-sponsored weeklong “Clinical Trials Methods in Neurology” course.

I will serve as co-Principal Investigator of the application for the “Identification of Effective CNS Therapies via a Continuous Clinical Trial”, and will direct the activities of the Data Coordinating Center (DCC). As the PI, I will have overall responsibility for all activities of the DCC. I will be responsible for overseeing and coordinating all components and training for the DCC including implementation, administration, and supervision of all research staff. I will also assist with the development of the data dictionary and electronic case report forms, serve as the liaison with the CCC, be responsible for all analyses and reports to the DSMB (including interim analyses, meeting abstracts, presentations, and manuscripts for publication).

B. 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), University of Iowa
08/10-Present	Director, CTSDMC, University of Iowa

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	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

Professional Affiliations: American Statistical Association; Biometrics Society – Eastern North America Region; Society of Clinical Trials

C. Selected Peer-reviewed Publications (Selected from over 70 peer-reviewed publications)

Coffey CS and Muller KE. Exact Test Size and Power of a Gaussian Error Linear Model for an Internal Pilot Study. *Stat Med*, 18, 1199-1214, 1999.

Coffey CS and Muller KE. Controlling Test Size While Gaining the Benefits on an Internal Pilot Design. *Biometrics*, 57, 625-631, 2001.

Ko DT, Hebert PR, **Coffey CS**, Sedrakyan A, Curtis JP, and Krumholz HM. Beta Blocker Therapy and Symptoms of Depression, Fatigue, and Sexual Dysfunction. *JAMA*, 288(3): 351-357, 2002.

Coffey CS, Steiner D, Baker BA, and Allison DB. A Randomized Double-Blind Placebo Controlled Clinical Trial of a Product Containing Ephedrine, Caffeine, and Other Ingredients from Herbal Sources for Treatment of Overweight and Obesity in the Absence of Lifestyle Treatment. *Int J Obes*, 28(11): 1411-1419, 2004.

Howard GH, **Coffey CS**, and Cutter GR. Is Bayesian Analysis Ready for Use in Phase III Randomized Clinical Trials 'Beware the Sound of the Sirens. *Stroke*, 36: 1622-1623, 2005.

Pergola PE, White CL, Graves JW, **Coffey CS**, Tonarelli SB, Hart RG, and Benavente OR for the SPS3 Investigators (2007). Reliability and Validity of Blood Pressure Measurement in the Secondary Prevention of Small Sub-cortical Strokes (SPS3) Study. *Blood Press Monit*, 12: 1-8, 2006.

Coffey CS, Kairalla JA, and Muller KE. Practical Methods for Bounding Type I Error Rate with an Internal Pilot Design. *Communications in Statistics – Theory and Methods*, 36: 2143-2157, 2007.

Gurka MJ, **Coffey CS**, and Muller KE. Internal Pilots for a Class of Linear Mixed Models With Gaussian and Compound Symmetric Data. *Stat Med*, 26: 4083-4099, 2007.

Coffey CS and Kairalla JA. Adaptive Designs: Progress and Challenges. *Drugs R D*, 9(4): 229-242, 2008.

Elkind MSV, Luna JM, **Coffey CS**, McClure LA, Liu KM, Spitalnik S, Paik MC, roldan A, White C, Hart R, and Benavente O. The Levels of Inflammatory Markers in the Treatment of Stroke (LIMITS) Study: inflammatory Biomarkers as Risk Predictors after Lacunar Stroke. *Int J Stroke*, 5(2)117-125, 2010. PMCID: PMC2918656.

Kairalla JA, Muller KE, and **Coffey CS**. Combining an Internal Pilot With An Interim Analysis For Single Degree of Freedom Tests. *Communications in Statistics – Theory & Methods*, 39(20): 3717-3738, 2010.

Gurka MJ, **Coffey CS**, and Gurka KK. Internal Pilots for Observational Studies. *Biometrical Journal*, 52(5): 590-603, 2010.

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. 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, 2011.

Coffey CS, Asselbergs FW, Hebert PR, Hillege HL, Li Q, Moore JH, and van Gilst WH. The Association of the Metabolic Syndrome with PAI-1 and t-PA Levels.

Benavente OR, White CL, Pearce L, Pergola P, Roldan A, Benavente M, **Coffey CS**, McClure LA, Szychowski JM, Conwit R, Heberling PA, Howard G, Bazan C, Vidal-Pergola G, Talbert R, and Hart RG for the SPS3 Investigators. The Secondary Prevention of Small Subcortical Strokes (SPS3) Study. *International Journal of Stroke*, 164-175.

D. Research Support

Ongoing Research Support

5 RO1 HL091843-04

NIH/NHLBI 4/15/09-8/31/13

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

The CTSDMC at the University of Iowa is serving as the Data Coordinating Center for the Collaboration Among Pharmacists and Physicians to Influence Outcome Measures Now (CAPTION) study. This NHLBI-funded prospective, cluster-randomized trial plans to enroll 1134 subjects from 27 clinics across the US, matched and randomized to the active intervention (2groups) or a control group. The objective is to conduct a large multi-center clinical trial in clinics with geographic, racial, and ethnic diversity to enhance the implementation and maintenance of a novel method for promoting blood pressure control in the clinic setting. The DCC supports all data collection, data management, clinical site monitoring, and statistical analyses for the study.

Role: Principal Investigator

The Parkinson's Progression Markers Initiative Statistics Core 10/01/09 – 03/31/15

The Michael J. Fox Foundation for Parkinson's Research

The University of Iowa is serving as the statistics core for the Parkinson's Progression Markers Initiative. This is a long-term study funded by the Michael J. Fox Foundation 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's disease progression markers to identify quantitative individual measures or combinations of measures that demonstrate optimum interval change in PD patients in comparison to healthy controls, or in subsets of PD patients defined by their baseline assessments. The statistics core serves to: 1) work with other investigators to ensure that all data transfers are complete, 2) assists with data checking, 3) assists investigators with study planning and protocol development, 4) has primary responsibility for all main study analyses, and 5) provides assistance to users of the PD-BIN database.

Role: Head of Statistical Core

U01-NS038529-05A1 (Oscar R. Benavente, MD, PI)

University of British Columbia (NIH/NHLBI) 12/01/09-12/31/12

Secondary Prevention of Small Subcortical Strokes (SPS3)

SPS3 consists of two randomized, multicenter clinical trials that follow a 3 year NINDS-sponsored pilot study. It will enroll 2500 participants (20% of whom will be Hispanic-Americans) with symptomatic, MRI-defined S3 without carotid stenosis or major cardiac sources of embolism at 35 clinical sites. Patients will be assigned, in a factorial design, to two interventions: 1) Antiplatelet therapy: aspirin 325 mg/day vs. aspirin 325 mg/day plus clopidogrel 75 mg/day and 2) Blood Pressure Intervention: SBP targets of 130-149 mmHg vs. <130 mmHg. Main outcomes to be considered are recurrent stroke (ischemic and hemorrhagic), cognitive decline, and major vascular events.

Role: PI of Subcontract

LRRK2 Cohort Consortium-Statistics

The Michael J. Fox Foundation for Parkinson's Research 6/02/11-6/01/13

The Statistics Team of LRRK2 conducts on-going 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: Statistics PI

UF11128 University of Florida (Nelson, David R.)

Adaptive Comparative Effectiveness Trials for Comparing Two Treatments 5/23/11-3/31/12

To access the use of adaptive sample size re-estimation (SSR) within comparative effectiveness research (CER) and develop and promote defensible guidelines for their use. This is a joint collaboration between the University of Florida and University of Iowa CTSA programs.

Role: PI of Subcontract; Biostatistician

1 U01 NS077108-01 (Coffey, Christopher)
National Institute of Health/NINDS
Amitriptyline and Topiramate in the Prevention of Childhood Migraine: DCC 10/1/11-9/30/16
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: Principal Investigator, Data Coordinating Center

1 U01 NS077352-01 (Coffey, Christopher)
National Institute of Health/NINDS
Network of Excellence in Neuroscience Clinical Trials (NEXT) - DCC 10/1/11-9/30/18
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 more rapid evaluation of promising treatments in neuroscience, and be a model that can be replicated across a number of studies and diseases.
Role: Principal Investigator, Data Coordinating Center

Completed Research Support

Levels of Inflammatory Markers in the Treatment of Stroke
PI: Mitchell E. Elkind (Columbia University) 05/25/05-04/30/09
R01 NS050724 NIH
This ancillary study to the multi-center, NINDS-funded Secondary Prevention of Small Subcortical Strokes (SPS3; P.I. O. Benavente) trial is a prospective study of inflammatory markers as risk factors for stroke and other vascular events in stroke survivors. The markers examined will include high sensitivity C-reactive protein, SAA, IL6, TNF, and TNF receptors.
Role: PI of subcontract

Pharmacogenomics in Pulmonary Arterial Hypertension
PI: Raymond L. Benza 09/01/05-07/31/09

R01 DK067487 NIH
This grant will determine clinically in PAH patients if associations exist between the efficacy and toxicity of sitaxsentan and bosentan and several gene polymorphisms in several key-disease and therapy specific genes. The grant will also characterize the relationship between these polymorphisms and PAH severity using either baseline hemodynamic or clinical surrogates for disease severity.
Role: Primary Statistician

Internal Pilots for Repeated Measures ANOVA
PI – LE Edwards (University of North Carolina) [Subcontract] 01/15/2003 to 12/31/2007

R01 CA095749-01A1 NIH
This grant proposes to study the use of internal pilots with repeated measures. We will develop better statistical algorithms for the univariate approach to repeated measures (UNIREP ANOVA), including exact properties and more accurate approximations. We will also derive exact and approximate properties of the distribution of the final sample size of internal pilot designs used with UNIREP ANOVA. Finally, we will describe analytic properties of UNIREP ANOVA in internal pilot designs, including some exact and large sample distributions, as well as practical algorithms.
Role: Coffey, CS (PI of subcontract)