

BIOGRAPHICAL SKETCH

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| | | | |
|--|-----------------------------|-------|----------------|
| NAME Christopher S. Coffey | POSITION TITLE 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

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 (from over 90 peer-reviewed publications)

1. Yeatts SD, Martin RH, Coffey CS, Lyden PD, Foster LD, Woolson RF, Broderick JP, Palesch YY. (2014) The challenges of decision making regarding futility in a randomized trial: The IMS-III experience. *Stroke*. 45(5):1408-1414. PMC: PMC4018452 PMID: 24699059
2. Morgan C, Huyck S, Jenkins M, Chen L, Bedding A, Coffey CS, Gaydos B, Wathen J. (2014) Adaptive design: Results of 2012 survey on perception and use. *Therapeutic Innovation & Regulatory Science*. 48(4):473-481.
3. 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 JL, Yeatts SD, Jinnah HA. (2014) Designing clinical trials for dystonia. *Neurotherapeutics*, 11(1), 117-127. PMC: PMC3899487, PMID: 24282121

4. Kang JH, Irwin DJ, Chen-Plotkin AS, Siderowf A, Caspell C, Coffey CS, Waligorska T, Taylor P, Pan S, Frasier M, Marek L, Kieburtz 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 β -amyloid 1-42, T-tau, P-tau181, and α -synuclein levels with clinical features of early drug naive Parkinson's Disease patients. *JAMA Neurology*, 70(10), 1277-1287. PMID: 23979011
5. The SPS3 Investigators, Benevente OR, Coffey CS, Conwit R, Hart RG, McClure LA, Pearce LA, Pergola PE, Szychowski JM. (2013) Effects of blood pressure targets in patients with recent lacunar stroke: The SPS3 randomized trial. *Lancet*, 382(9891), 507-515. PMID: 23726159
6. Carter BL, Coffey CS, Uribe L, James PA, Egan BM, Arderu G, Chrischilles EA, Ecklund D, VanderWeg M, 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. PMC: PMC3683891, PMID: 23730989
7. Hershey AD, Powers SW, Coffey CS, Ecklund D, Chamberlin LA, 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. *Headache*, 53(5), 799-816. PMC: PMC3637406, PMID: 23594025
8. McClure LA, Coffey CS, Howard GH. (2013) Monitoring futility in a two-by-two factorial design: the SPS3 experience. *Clinical Trials*, 10(2), 250-256. PMC: PMC3731445, PMID: 23378483
9. Coffey CS, Levin B, Clark C, Timmerman C, Wittes J, Gilbert P, 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
10. McClure LA, Szychowski JM, Benevente O, Coffey CS. (2012) Sample size re-estimation in an ongoing NIH-sponsored clinical trial: The Secondary Prevention of Small Subcortical Strokes experience. *Contemporary Clinical Trials*, 33(5), 1088-1093. PMC: 22750086, PMID: PMC3408857
11. Kairalla JA, Coffey CS, Thomann MA, Muller KE. (2012) Adaptive trial designs: A review of barriers and opportunities. *Trials*, 13, 145. PMC: PMID: 22917111, PMID: PMID: PMCID: PMC2519822
12. The SPS3 Investigators, (Writing Group: Benavente,, OR, McClure LA, Coffey C, Szychowski JM, Pearce LA, Hart RG). (2012) Effects of clopidogrel added to aspirin in patients with recent lacunar stroke. *New England Journal of Medicine*, 367(9), 817-825. PMC: PMID: 22931315
13. Clifton GL, Valadka A, Zygun D, Coffey CS, Drever P, Fourwinds S, Janis LS, Wilder E, Taylor P, Harshman K, Conley A, Puccio A, Levin HS, McCauley SR, Bucholz RD, Smith KR, Schmidt JH, Scott JN, Yonas H, 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.
14. Coffey CS, Muller KE. (2003) Properties of internal pilots with the univariate approach to repeated measures. *Statistics in Medicine*, 22, 2469-2485.
15. Coffey CS, Muller KE. (2001) Controlling test size while gaining the benefits of an internal pilot design. *Biometrics*, 57, 625-631.

D. Research Support

Ongoing Research Support

5 RO1 HL091843 (Coffey, Christopher)

NIH/NHLBI

4/15/09-2/28/15

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 (2 groups) 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

6/24/10 – 6/21/18

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

LRRK2 Cohort Consortium-Statistics

The Michael J. Fox Foundation for Parkinson's Research

6/2/11-12/31/14

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

5 U01 NS077108 (Coffey, Christopher)

National Institute of Health/NINDS

Amitriptyline and Topiramate in the Prevention of Childhood Migraine: DCC

9/30/11-8/31/16

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

5 U01 NS077352 (Coffey, Christopher)

National Institute of Health/NINDS

Network of Excellence in Neuroscience Clinical Trials (NEXT) - DCC

9/30/11-6/30/18

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

PPMI 2013 (Coffey, Christopher)

The Michael J Fox Foundation for Parkinson's Research

3/1/14-2/28/19

Three Site Assessment of the Potential for Home Dexterity Monitoring in a PD Biomarker Study (TAP-PD), a Parkinson's Progression Markers Initiative (PPMI) Sub-Study

"Expanded support for Stats Core-supplement." PPMI Sub-study to participate in an ancillary project focused on assessing an objective measurement device entitled "Three Site Assessment of the Potential for Home Dexterity Monitoring in a PD Biomarker Study (TAP-PD), A Parkinson's Progression Markers Initiative (PPMI) Sub-study." The PPMI Statistics Core will provide analysis of data collected through TAP-PD.

Role: Contact Principal Investigator

1 R18 HL116259-01A1 (Carter, Barry)

National Institute of Health

4/1/14-3/31/19

MEDication Focused Outpatient Care for Underutilization of Secondary Prevention

The primary aim is to determine if a web-based centralized cardiovascular risk service (CVRS) managed by clinical pharmacists will be implemented within diverse primary care offices to help prevent death caused by cardiovascular disease.

Role: Co-Investigator

Completed Research Support

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)