OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Stephen D. Simon

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

POSITION TITLE: Professor / Independent Statistical Consultant

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 Iowa | B.A. | 06/77 | Mathematics |
| University of Iowa | M.S. | 12/78 | Statistics |
| University of Iowa | Ph.D. | 12/82 | Statistics |

# A. Personal Statement

# As a statistical consultant with over 35 years of experience, I have worked on pretty much any type of study imaginable, though I have specialized mostly in health care research since 1987. I have taught many formal and informal training classes in the use of SQL and of statistical software (SAS, SPSS, and R). I am currently the President of the Kansas City R Users Group and have given many presentations for them. With the assistance of a database administrator, I am developing a new class, Introduction to SQL, as I have found SQL to be vital in any analysis of electronic health record data.

# I have an outstanding track record in dissemination of research results. I have over 100 peer reviewed publications, four of which have won major awards. I have published a book about the statistical aspects of Evidence-Based Medicine and am the author of a major website and blog (www.pmean.com, blog.pmean.com) with over 2,000 pages about Statistics, Evidence-Based Medicine, and research ethics.

# B. Positions and Honors

**Positions and Employment**

1979 – 1981 Research Assistant, Statistical Consulting Center, University of Iowa

1981 – 1987 Assistant Professor, Department of Applied Statistics and Operations Research, Bowling Green State University, Bowling Green, Ohio

1987 – 1987 Research Statistician, Division of Biomedical and Behavioral Science, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Cincinnati, Ohio

1987 – 1996 Chief, Statistics Activity, Division of Biomedical and Behavioral Science, National Institute for Occupational Safety and Health, Cincinnati, Ohio

1996 – 2008 Research Biostatistician, Office of Medical Research, Children’s Mercy Hospital, Kansas City, Missouri, with an adjunct faculty appointment at the University of Missouri-Kansas City

2008 – present Part-time Independent Statistical Consultant, P.Mean Consulting, Leawood, Kansas

2008 – present Part-time Professor (currently 44% effort), Department of Biomedical and Health Informatics, University of Missouri-Kansas City, Kansas City, Missouri

Other Experience and Professional Memberships

1984 - present Member, American Statistical Association

Honors

1990 Public Health Service Achievement Medal given for producing cost savings and greater operational efficiency through the use of micro-computer analysis of statistical data.

1990 Alice Hamilton Award given to a paper I co-authored (Schrader et al Reproductive Toxicology 1988; 2: 183-190).

1991 Alice Hamilton Award given to a paper I co-authored (Schrader et al Reproductive Toxicology 1988; 2: 183-190).

1994 Public Health Service Commendation Medal given in July 1994 for my oversight of a laboratory modernization effort.

1997 Best presentation in the area of Teaching Statistics in the Health Sciences given for a talk at the Joint Statistical Meetings in Anaheim CA (Simon "Medical Statistics Case Studies on the Web").

1999 Alice Hamilton Award (Biological Sciences Category) given to a paper I co-authored (Moorman et al Reproductive Toxicology 1998;12(3):333-46).

2003 Editor's Award given to a paper I coauthored (Miller et al Am J Audiology 2003;24(1);16-18).

2012 Honorable mention and $1,000 cash award given for R code that I submitted to the Applications of R in Business competition sponsored by Revolution Analytics.

# C. Contribution to Science

1. I’ve had the opportunity to work with many researchers and the biggest problem that most of them face is **poor patient accrual**. They struggle to find a way to recruit subjects quickly enough so that they could meet their sample size goals within a practical time frame. With a colleague at Kansas University Medical Center (KUMC), Byron Gajewski, and later with a graduate student at KUMC, Joyce Yu Jiang, we developed Bayesian models that could forecast the amount of time that a trial would take to reach a fixed sample size or to forecast the sample size for a trial that ended at a fixed date.

My work with accrual models have taught me that, by itself, the sample size calculation during the planning of a research study is insufficient. If it takes you ten years to complete a study that you thought would only take ten months, you are going to end up with a disaster.

a. Jiang Y, Simon S, Mayo MS, Gajewski BJ. Modeling and validating Bayesian accrual models on clinical data and simulations using adaptive priors. Stat Med. 2015 Feb 20; 34(4): 613-29.

b. Gajewski BJ, Simon SD. A One-Hour Training Seminar on Bayesian Statistics for Nursing Graduate Students. The American Statistician. August 1, 2008, 62(3): 190-194.

c. Gajewski BJ, Simon SD, Carlson SE. Predicting accrual in clinical trials with Bayesian posterior predictive distributions. Stat Med. 2008 Jun 15;27(13):2328-40.

2. At Children’s Mercy Hospital, I developed an interest in **Evidence Based Medicine**. I had attended many journal clubs and started wondering what level of evidence it takes to get doctors or other health care professionals to change their clinical practice. In my experience, doctors tended to be hypercritical of the research presented at journal clubs. It’s far too easy to nitpick and find a minor issue, but this does not necessarily invalidate the findings of the study.

I presented some of my own views on critical appraisal in a series of articles for the Journal of Andrology. I also partnered with doctors to write a couple of editorials that addressed controversies in critical appraisal, especially the importance of defining a clinically important difference. The material from these articles and editorials plus additional content from my website formed the basis of a book published in 2006 by Oxford University Press.

My experience with Evidence Based Medicine has taught me the importance of a thoughtful approach to research design issues like blinding and concealed allocation so that the resulting research publications will be considered more persuasive during the critical appraisal step of Evidence Based Medicine.

a. Simon SD. Statistical Evidence in Medical Trials. What Do the Data Really Tell Us? Oxford UK: Oxford University Press; 2006.

b. Portnoy JM, Simon SD. Is 3-mm less drowsiness important?. Ann Allergy Asthma Immunol. 2003 Oct;91(4):324-5.

c. Simon SD. Understanding the odds ratio and the relative risk. J Androl. 2001 Jul-Aug;22(4):533-6.

3. At the National Institute for Occupational Safety and Health (NIOSH), a branch of the Centers for Disease Control and Prevention, I worked with a toxicologist, Steven M. Schrader, on **male reproductive toxicology**. I should note that Dr. Schrader also supervised a strong program in female reproductive toxicology, and while I learned quite a bit about both sides of the equation, a different statistician served as co-author on the publications on female reproductive toxicology.

I was fortunate to arrive at NIOSH shortly after completion of a major longitudinal study of sperm samples in a healthy cohort of unexposed males. The longitudinal design required novel statistical measures and graphical displays. This data set produced many publications including two which won major awards.

In addition to the longitudinal study, I worked on the planning of studies in humans examining occupational exposures to non-ionizing radiation and lead, and helped develop a novel rabbit model for lead exposure.

My research in male reproductive toxicology taught me how to handle the complexities associated with longitudinal data and exposure studies.

a. Grajewski B, Cox C, Schrader SM, Murray WE, Edwards RM, Turner TW, Smith JM, Shekar SS, Evenson DP, Simon SD, Conover DL. Semen quality and hormone levels among radiofrequency heater operators. J Occup Environ Med. 2000 Oct;42(10):993-1005.

b. Schrader SM, Langford RE, Turner TW, Breitenstein MJ, Clark JC, Jenkins BL, Lundy DO, Simon SD, Weyandt TB. Reproductive function in relation to duty assignments among military personnel. Reprod Toxicol. 1998 Jul-Aug;12(4):465-8.

c. Moorman WJ, Skaggs SR, Clark JC, Turner TW, Sharpnack DD, Murrell JA, Simon SD, Chapin RE, Schrader SM. Male reproductive effects of lead, including species extrapolation for the rabbit model. Reprod Toxicol. 1998 May-Jun;12(3):333-46.

d. Schrader SM, Turner TW, Breitenstein MJ, Simon SD. Longitudinal study of semen quality of unexposed workers. I. Study overview. Reprod Toxicol. 1988;2(3-4):183-90.

4. At Bowling Green State University, I partnered with an Economics faculty, James P. Lesage, to study **numerical accuracy issues**. These publications started with the seminal data set for numerical accuracy, the Longley data set, and looked at a flexible alternative developed by Wampler. We developed an extension that could examine near collinearity involving the intercept and produced new benchmarks for Analysis of Variance.

Some of these benchmarks were adopted by the National Institute for Standards and Technology for their Statistical Reference Datasets project. I also produced a couple of pedagogical articles that clearly illustrated how problems with numerical accuracy can arise.

The work in this area gave me an early overview of the broad range of statistical software packages available for microcomputers. I have maintained this interest and can easily identify which, among several competing statistical packages, is the best for a particular data analysis.

a. Simon SD, Lesage JP. Assessing the accuracy of ANOVA calculations in statistical software. Computational Statistics and Data Analysis 1990: 8(3); 325-332.

b. Simon SD, Lesage JP. The impact of collinearity involving the intercept term on the numerical accuracy of regression. Computer Science in Economics and Management 1988: 1; 137-152.

c. Simon SD. How to illustrate numerical accuracy problems on any computer. Mathematics and Computer Education 1987: 21(1); 11-15.

d. Simon SD. To err isn’t only human. Computer Language 1986: 3(3); 71-76.

# Complete List of Published Work in MyBibliography: http://www.ncbi.nlm.nih.gov/sites/myncbi/stephen.simon.1/bibliography/48071026/public/?sort=date&direction=descending

# D. Research Support

**Ongoing Research Support**

Our Healthy Jackson County (Jackson County funding, Principal Investigator: Jannette Berkley-Patton). This is a continuation and expansion of the Our Healthy Kansas City Eastside grant. It represents a community-wide initiative that promotes and delivers widespread COVID-19 vaccinations and other health services to residents of Jackson County. More than 60 community organizations and health agencies are partnering with us to support healthy lifestyles through vaccine events and health screenings like blood pressure checks, diabetes screenings and dental education. I am a co-investigator funded at 5% effort from July 2023 through June 2024.

Faithful Response II: COVID-19 Rapid Test-to-Treat with African American Churches (U01MD018310, Principal Investigator: Jannette Berkley-Patton) The primary aim of this study is to fully test a culturally/religiously-tailored, church-based COVID-19 test-to-treat with linkage-to-care intervention condition against a non-tailored education condition on COVID-19 rapid testing rates at 6 months with adult African-American church members and the community members they serve. I am a co-investigator funded at 5% effort from November 2022 to October 2024.

Impact Lead - Kansas City (HHTS20000276, Housing and Urban Development, Principal Investigator: Steve Simon). We propose a data collection effort to show that lead safe interventions can be targeted more effectively and that they can inform decisions about the choices among intervention strategies. Our first aim is to quantify the extent to which remediations to make housing lead safe by HUD standards leads to fewer lead poisoned children among those who move in. Our second aim is to develop an exterior housing-based risk index to cost effectively target homes with higher interior lead dust levels. I am the principal investigator funded at 13.5% effort from January 2021 through December 2024.

Development of a telehealth obesity intervention for patients with MS. (Multiple Sclerosis Society, Principal Investigator: Jared Bruce) A cross-disciplinary research team is testing the effectiveness of an MS-specific weigh loss/healthy living program delivered by phone, since obesity can profoundly worsen MS severity. I am a co-investigator funded at 1.5% effort starting in October 2019, increasing to 5% effort from October 2022 through September 2023 and dropping back to 1.5% effort from October 2023 to September 2024.

**Completed Research Support in the Past Three Years**

Our Healthy Kansas City Eastside (Jackson County funding, Principal Investigator: Jannette Berkley-Patton). This is a community-wide initiative that promotes and delivers widespread COVID-19 vaccinations and other health services to residents on the east side of Kansas City. I was a co-investigator funded at 5% effort from July 2022 through March 2023.

Preschool Development Grant Birth through Five Initiative (90TP0066-01, Missouri Department of Elementary and Secondary Education, Principal Investigator: Mike Abel). We present best practices for professionals and programs across Missouri's early childhood mixed-delivery system. I was funded at 5% effort from September to December 2020.

Frontiers: University of Kansas Clinical and Translational Science Institute (NIH 5UL1TR002366-04, Principal Investigator: Mario Castro). The Heartland Institute for Clinical and Translational Research has been a catalyst for bringing together translational science investigators and stakeholders across the KC region, and beyond.. I was funded at 10% effort from September 2017 through June 2021.