CURRICULUM VITAE

Scott Shields Emerson, M.D., Ph.D.

1. Date: August 18, 2012

2. Biographical Information

Professor of Biostatistics
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3. Education

University of Virginia, Charlottesville, Virginia, B.A., Physics, 1977
University of Virginia, Charlottesville, Virginia, M.D., Medicine, 1981
University of Virginia, Charlottesville, Virginia, M.C.S., Computer Science, 1984
University of Washington, Seattle, Washington, Ph.D., Biostatistics, 1988

4. Licensure: not applicable

5. Professional Positions

Postdoctoral Fellow, Department of Biomedical Engineering, University of Virginia, 1981-84
Senior Fellow, Department of Biostatistics, University of Washington, 1984-88
Assistant Professor, Division of Biostatistics, Department of Statistics, University of Florida, 1988-89
Research Assistant Professor, Department of Family and Community Medicine, University of Arizona, 1989-95
Research Associate, Arizona Cancer Center, University of Arizona, 1989-95
Associate Professor, Department of Statistics, University of Arizona, 1992-95
Member, Applied Mathematics, University of Arizona, 1993-95
Associate Professor, Department of Biostatistics, University of Washington, 1995-1999
Associate Member, Division of Public Health Sciences, Fred Hutchinson Cancer Research Center, 1995-2000
Professor, Department of Biostatistics, University of Washington, 1999-present
Graduate Program Coordinator, Department of Biostatistics University of Washington, 2002-2005

6. Honors, Awards, Scholarships

Honor Award Scholarship, University of Virginia (1973-77)
Echols Scholar, University of Virginia (1973-77)
Phi Beta Kappa (1977)
NLM Fellowship, Computer Applications to Medicine (1981-84)
NCI Fellowship, Cancer Epidemiology and Biostatistics (1984-88)

Donovan J. Thompson Award, University of Washington (1985)
WNAR Student Paper Competition, Runner-up (1988)
Best Special Contributed Paper, Section on Teaching Statistics in the Health Sciences, American Statistical Association, 1997 Joint Statistical Meetings
Outstanding Teaching Award, School of Public Health, 1999
Fellow, American Statistical Association, 2008
Best Contributed Paper, Section on Teaching Statistics in the Health Sciences, American Statistical Association, 2008 Joint Statistical Meetings

7. Professional Activities (outside of UW)

Organizer and chair of Joint IMS/WNAR Invited Paper Session: Ethical Issues in Clinical Trials, IMS/WNAR Western Regional Conference, Santa Barbara, California, July 1991.
Organizer of ENAR Invited Paper Session: Estimation After Sequential Stopping, ENAR Regional Conference, Cincinnati, Ohio, March 1992.
Organizer and chair of Invited Paper Session: Statistical Methods for the Detection of Interactions Between Drugs, 1992 Joint Statistical Meeting, Boston Massachusetts, August, 1992.
Invited participant, National Cancer Institute Workshop on Markers of Colon Cell Proliferation, Bethesda, Maryland, October, 1992.
Organizer and Chair of Invited Paper Session: Biostatistics Service Courses for Health Sciences Researchers: Where Should We Be in 2007? 1997 Joint Statistical Meeting, Anaheim, California, August 1997.
Organizer and Chair of Invited Paper Session: Time-Varying Treatment Effects in Clinical Trials, 2005 Annual Meeting, WNAR, Fairbanks, Alaska, June, 2005.

Membership in Professional Organizations:

American Statistical Association
Program Chair, Section on Epidemiology, 1995-96
Biometric Society
Member, Regional Advisory Board, 1993-95
WNAR Representative to Program Committee, 1995 Joint Statistical Meetings
President , WNAR, 1999
Society of Clinical Trials

Editorial Boards:

Associate Editor, American Journal of Epidemiology (1993-97)
Statistical Editor, Journal of the National Cancer Institute (1995-2003)
Member, Editorial Board, Sequential Analysis (1996-present)
Review of manuscripts submitted for publication to:
Journal of the American Statistical Association, Journal of the Royal Statistical Society, Series B, Controlled Clinical Trials, Biometrics, American Journal of Epidemiology, The American Statistician, Statistics in Medicine, Journal of Statistical Planning and Inference, American Journal of Public Health, Communications in Statistics-Theory and Methods, Biometrical Journal, Journal of the National Cancer Institute, The Statistician, Cancer Research, Lifetime Data Analysis, Clinical Chemistry

Appointments, Advisory Boards and Review Committees:

Member, ad hoc NCI Technical Review Group for the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial - Study Coordinating and Data Management Center, June 1991.
Member, ad hoc NCI Technical Review Groups for the Prostate Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial - Screening Centers, August, 1991.
Member, ad hoc NHLBI Special Emphasis Panel for the evaluation of the Data Coordinating Center and Clinical Centers for the Clinical Network for the Treatment of Adult Respiratory Distress Syndrome, April, 1994.
Member, NCI Site Visit Committee, University of Pennsylvania Cancer Center core Grant Application.
Member, NHLBI Site Visit Committee, Data Coordinating Center for the Clinical Network for the Treatment of Adult Respiratory Distress Syndrome, April 1994.
Member, Protocol Review Committee, Adult Respiratory Distress Syndrome Network, NHLBI, 1995-2004.
Member, ad hoc NIAMS Technical Review Group for Data Integrity Assessments for NIAMS Clinical Trials, May 1996.
Member, Data Safety Monitoring Committee, Multicenter Clinical Trial of E5 in Gram Negative Sepsis, Pfizer, Inc. and Xoma Corporation.
Member, Data Safety Monitoring Committee, Multicenter Clinical Trial of rhuMAb HER2 in Breast Cancer, Genentech Corporation.
Member, NCI Special Emphasis Panel for PLCO Expansion, July 1997.
Member, Data Safety Monitoring Board, Phase II Clinical Trials of rhu Mab CD18, Protodigm.
Member, ad hoc NCI Review Group for Breast Cancer Screening Trial, January 1998
Member, ad hoc NCI Review Group for NSABP, April, 1998
Member, Data Safety Monitoring Committee, Multicenter Clinical Trial of BPI in Trauma Patients, Xoma Corporation
Member, ad hoc NCI Review Group for PLCO Expansion, June-August, 1998
Member, Data Safety Monitoring Board, Clinical Trial of Apheresis Column in Rheumatoid Arthritis, Otsuka Corporation
Member, Data Safety Monitoring Board, Clinical Trials of Histamine in Malignant Melanoma and Acute Myelogenous Leukemia, Maxim Pharmaceuticals
Member, Data Safety Monitoring Board, LIMIT Trial, Genentech Corporation
Chair, Data Safety Monitoring Board, Clinical Trial of anti-CD11 in Psoriasis, Genentech
Member, Data Safety Monitoring Board, Clinical Trial of Efalizumab in Rheumatoid Arthritis, Xoma/Genentech
Member, Data Safety Monitoring Board, Clinical Trial of Vaccine in Lung Cancer, Biomira
Member, Data Safety Monitoring Board, DFMO and Sulindac in Colon Polyp Prevention, University of California Irvine (NCI sponsored)
Chair, Data Safety Monitoring Board, Clinical Trials of Histamine in Malignant Melanoma, Maxim Pharmaceuticals
Member, Data Safety Monitoring Board, National Lung Screening Trial, National Cancer Institute
Member, FDA Reproductive Drugs Scientific Advisory Panel 2002 - 2006
Member, Data Safety Monitoring Board, Clinical Trials of rTFPI in Severe Community Acquired Pneumonia, Chiron
Member, Internal Data Safety Monitoring Board, Clinical Trial of Aspirin and Biology of the Colon, Fred Hutchinson Cancer Research Center (NIH sponsored)

Member, Data Safety Monitoring Board, Clinical Trials of Rituximab in Multiple Sclerosis, Genentech
Member, Data Safety Monitoring Board, Clinical Trials of Xolair in Peanut Allergy, Genentech
Member, Data Safety Monitoring Board, Clinical Trials of Phenoptin in Phenylketonuria, Biomarin
Member, Data Safety Monitoring Board, Clinical Trial in Gastointestinal Stromal Tumors, Agouron
Member, Data Safety Monitoring Board, Clinical Trial in Metastatic Breast Cancer, Agouron
Member, Data Safety Monitoring Board, Clinical Trial in Renal Cell Cancer, Agouron
Member, Data Safety Monitoring Board, Clinical Trial in Cystic Fibrosis, Chiron
Member, Data Safety Monitoring Board, Clinical Trial in Hepatitis C Infection, Valeant
Member, Data Safety Monitoring Board, International AIDS clinical trials, NIAID, NIH
Member, NIH State of the Science Conference Panel on Management of Menopause-Related Symptoms, March 21-23, 2005
Member, Data Safety Monitoring Board, Clinical Trial in Non-Small Cell Lung Cancer, Bayer
Member, Data Safety Monitoring Board, Clinical Trial in Biliary Tumors, Helsinn
Member, Data Safety Monitoring Board, Clinical Trial in Treatment of Nausea and Vomiting in Chemotherapy, Glaxo Smith-Kline
Chair, Data Safety Monitoring Board, Clinical Trial of Massage in Lower Back Pain, Group Health Cooperative (NIH sponsored)
Member, Data Safety Monitoring Board, Clinical Trials in Breast Cancer, Pfizer
Member, Data Safety Monitoring Board, Clinical Trials in Pancreatic Cancer, Pfizer
Member, Clinical Trials Review Committee, NHLBI, 2007-2011.
Member, Data Safety Monitoring Board, Clinical Trial in Aspergillosis, Pfizer
Chair, Data Safety Monitoring Board, Clinical Trial in Lung Transplantation, APT
Member, Data Safety Monitoring Board, Clinical Trial in Chronic Kidney Disease, Novartis
Member, National Academy of Sciences Oversight Committee on Missing Data in Clinical Trials
Member, FDA Cardiorenal Drugs Scientific Advisory Committee 2011 - 2014

8. Bibliography

a) Refereed research articles (* denotes role as primary mentor for first author)

1. Green SJ, Fleming TR, **Emerson SS**: Effects on overviews of early stopping rules for individual trials. *Statistics in Medicine* 6:361-367, 1987.

2. Adamus G, Zam ZS, **Emerson SS**, Hargrave PA: Monoclonal antibody production: A simple method for rescuing desired hybridomas. *In Vitro Cellular and Developmental Biology* 25:1141-1146, 1989.

3. **Emerson SS**, Fleming TR: Symmetric group sequential test designs. *Biometrics* 45:905-923, 1989.

4. **Emerson SS**, Fleming TR: Contribution to the discussion of: "Interim Analyses: the repeated confidence interval approach." by Jennison C, Turnbull BW. *J Royal Stat Soc (B)* 51:305-361, 1989.

5. Lanciani CA, Giesel JT, Anderson JF, **Emerson SS**: Photoperiod-induced changes in metabolic response to temperature in drosophila melanogaster. *Functional Ecology* 4:126-133, 1990.

6. Virapongse C, **Emerson S**, Li KCP, Martineau BS, Staab EV: Research resources in radiology. *Radiology* 175:247-251, 1990.

7. Dinerman J, Mehta JL, Saldeen TGP, **Emerson S**, Wallin R, Davda R, Davidson A: Increased neutrophil elastase activity in unstable angina pectoris and acute myocardial infarction. *J Am Coll Cardiol* 15:1559-1563, 1990.

8. **Emerson SS**, Fleming TR: Parameter estimation following group sequential hypothesis testing. *Biometrika* 77:875-892, 1990.

9. **Emerson SS**, Fleming TR: Interim analyses in clinical trials. *Oncology* 4:41-51, 1990.

10. Guy J, Ellis EA, Hope GM, **Emerson S**: Maintenance of myelinated fibre G ratio in acute experimental allergic encephalomyelitis. *Brain* 114:281-294, 1991.

11. Lehnert M, Dalton W, Roe D, **Emerson S**, Salmon S: Synergistic inhibition by verapamil and quinine of P-glycoprotein-mediated multidrug resistance in a human myeloma cell line model. *Blood* 77:348-354, 1991.

12. Graham-Pole J, Gee A, **Emerson S**, Gallo J, Lee C, Luzins J, Janssen WE, Pick T, Worthington-White D, Elfenbein G, Gross S, Weiner R: Myeloablative chemoradiotherapy and autologous bone marrow infusions for treatment of neuroblastoma: Factors influencing engraftment. *Blood* 78:1607-1614, 1991.

13. Vargas PA, Alberts DS, Ritenbaugh C, Atwood JR, Sampliner R, Earnest D, Ramanuhan P, McGee D, Clark L, **Emerson S**: Dietary fiber and colon cancer prevention. *Cancer Bulletin* 43:549-554, 1991.

14. Lehnert M, **Emerson S**, Dalton WS, Salmon SE: Identification of potentially useful chemosensitizers to reverse multidrug resistance. *Eur J Cancer* 27 (suppl 2):S210, 1991.

15. Otto PM, Otto RA, Virapongse C, Friedman SM, **Emerson S**, Li KC, Malot R, Kaude JV, Staab EV: Screening test for detection of metallic foreign objects in the orbit before magnetic resonance imaging. *Invest Radiol* 27:308-311, 1992.

16. McGuire TR, Yee GC, **Emerson S**, Gmur DJ, Carlin J: Pharmacodynamic studies of cyclosporine in marrow transplant recipients. A comparison of three assay methods. *Transplantation* 53:1272-1275, 1992.

17. Miller JI, Ahmann FR, **Emerson SS**, Botacini MR: The clinical usefulness of serum PSA following hormonal therapy of metastatic prostate cancer. *J Urol* 147:956-961, 1992.

18. Xu MJ, Plezia P, Alberts DS, **Emerson S**, Peng YM, Sayers S, Liu Y, Ritenbaugh C, Gensler H: Effect of chronic oral administration of beta-carotene on plasma alpha-tocopherol concentrations in an experimental mouse model and normal human subjects and UV irradiated mice. *J Nat Cancer Instit* 84:1559-1565, 1992.

19. **Emerson SS**, Emerson JC: Direct standardization of incidence rates in the presence of incomplete data. *Stat Med* 12:3-12, 1993.

20. **Emerson SS**, McGee DL, Fennerty B, Hixson L, Garewal H, Alberts D: Design and analysis of studies to reduce the incidence of colon polyps. *Stat Med* 12:339-351, 1993.

21. **Emerson SS**: Computation of the uniform minimum variance unbiased estimator of a normal mean following a group sequential test. *Comput Biomed Res* 26:69-73, 1993.

22. Weyman C, Graham-Pole J, **Emerson S**, August CS, Champlin RE, Coccia P, Fay J, Jarris RE, Koch P, Johnson FL, Pick T, Souillet G, Spruce W, Vega R, Willoughby MLN, Woods W: Use of cytosine arabinoside and total body irradiation as conditioning for allogeneic marrow transplantation in patients with acute lymphoblastic leukemia: A retrospective survey. *Bone Marrow Transplantation* 11:43-50, 1993.

23. Lahood N, **Emerson SS**, Kumar P, Sorenson RU: Antibody levels and response to pneumococcal vaccine in steroid dependent asthmatics. *Ann Allergy* 70:289-294, 1993.

24. Lehnert M, **Emerson S**, Dalton WS, de Giuli R, Salmon SE: In vitro evaluation of chemosensitizers for clinical reversal of P-glycoprotein-associated taxol resistance. *Journal of the National Cancer Institute Monographs* 15:63-67, 1993.

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42. Meyskens FL, Gerner FW, **Emerson S**, Pelot D, Durbin T, Doyle K, Lagerberg W: A randomized double-blind placebo-controlled phase IIb trial of difluoromethylornithine for colon cancer prevention. *J Nat Cancer Inst* 90:1212-1218, 1998.

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51. Emerson JF, **Emerson SS**: The impact of requisition design on laboratory utilization. *Am J Clin Pathol.* 116(6):879-84, Dec 2001.

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90. **Emerson SS**, Fleming TR. Adaptive methods: Telling the "rest of the story". *Journal of Biopharmaceutical Statistics* 2010 **20**: 1150-1165.

91. National Research Council. (2010). *The Prevention and Treatment of Missing Data in Clinical Trials.* Panel on Handling Missing Data in Clinical Trials. Committee on National Statistics, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press.

92. Hostler D, Everson-Steward S, Rea TD, Stiell IG, Callaway CW, Kudenchuk PJ, Sears GK, **Emerson** SS, Nichol G. A prospective cluster-randomized trial of real-time CPR feedback during out-of-hospital cardiac arrest resuscitation. *BMJ* 2011; 2011; 342:d512.

93. Bulger EM, May S, Kerby JD, **Emerson** S, Stiell IG, Schreiber MA, Brasel KJ, Tisherman SA, Coimbra R, Rizoli S, Minei JP, Hata JS,, Sopko G, Evans DC, Hoyt DB. Prehospital Hypertonic Resuscitation Following Traumatic Hypovolemic Shock: A Randomized, Placebo Controlled Trial. *Annals of Surgery* 2011 253(3):431-441.

94. Emerson SC, Rudser KD, **Emerson SS.** Exploring the benefits of adaptive sequential designs in time-to-event endpoint settings. *Statistics in Medicine* 2011 30(11): 1199-1217.

95. **Emerson SS**, Levin GP, Emerson SC. Comments on "Adaptive increase in sample size when interim results are promising: A practical guide with examples." *Statistics in Medicine* 2011 30:3285-3301.

96. Fleming TR, **Emerson SS**. Evaluating rivaroxaban for non-valvular atrial fibrillation – regulatory considerations. *New England Journal of Medicine* 2011 365(17).

97. Little RJ, Cohen ML, Dickersin K, **Emerson SS**, Farrar JT, Neaton JD, Shih W, Siegel JP, Stern H. The design and conduct of clinical trials to limit missing data. *Statistics in Medicine* 2012 (epub)

98. Fleming TR, **Emerson SS**. Evaluating rivaroxaban for non-valvular atrial fibrillation – regulatory considerations. *New England Journal of Medicine* 2011 365(17).

In Press

99. *****Devlin SM, Thomas E, **Emerson SS.** Parametric and semi-parametric ROC regression under model misspecification. *Communications in Statistics – Theory and Methods (in press*)

100. Little FJ, D'Agostino F, Cohen ML, Dickersin K, **Emerson SS**, Farrar JT, Frangakis C, Hogan JW, Molenberghs G, Murphy SA, Neaton JD, Rotnitzky A, Scharfstein D, Shih W, Siegel J, Stern H. The prevention and treatment of missing data in clinical trials. *New England Journal of Medicine* 2012 (to appear).

101. *****Rudser KD, LeBlanc ML, **Emerson SS**. Estimation for arbitrary functionals of survival. *Statistics in Medicine (in press*)

Submitted

102. *****Shoben A, Rudser KD, **Emerson SS.** Estimates of information growth in longitudinal clinical trials. (submitted*)*

103. *****Levin GP, Emerson SC, **Emerson SS.** Adaptive clinical trial designs with pre-specified rules for modifying the sample size based on the interim estimate of treatment effect (resubmitted to *Statistics in Medicine)*

104. Emerson SC, **Emerson SS.** Comments on "Outlier-sums for differential gene expression analysis". (resubmitted to *Biostatistics*)

105. **Emerson SS**, Kittelson JM, Gillen DL. On the use of stochastic curtailment in group sequential clinical trials. (Under revision for resubmission to *Statistics in Medicine)*.

106. Koprowicz K, **Emerson SS**, Hoff P. A comparison of parametric and coarsened Bayesian interval estimation in the presence of a known mean-variance relationship. (Under revision for resubmission to *Canadian Journal of Statistics*).

b) **Other refereed scholarly publications**

None

c) **Books and book chapters**

1. Emerson SS, Hesterberg T, Bruce AG, Kannapel L. *S+SeqTrial: An S+ Module for Clinical Trial Design.* Release 2, Insightful Corporation, 2002.

2. Alberts DS, Einspahr MS, McGee DL, Hixson LJ, Davidson J, **Emerson S**, Earnest DL: Reproducibility of *[^{3}H]* - thymidine labeling index determinations in rectal mucosa crypt organ culture. **In**: Calcium, Vitamin D, and Prevention of colon Cancer (M Lipkin, HL Newmar and G Kelloff, eds.). Boca Raton: CRC, 1991, pp. 327-337.

3. Meyskens FL, Pelot D, Meshkinpour H, Plezia P, Gerner EW, **Emerson S**: Preliminary results of phase IIa trial of difluoromethylornithine (DFMO) to prevent colon cancer. **In:** Cancer Chemoprevention (Wattenberg, *et al*., eds.). Boca Raton: CRC Press, 1992.

4. Lehnert M, **Emerson S**, Dalton WS, Salmon SE: Reversal of MDR1: How to evaluate clinical usefulness of chemsentizers in vitro. **In:** The Clinical Value of Drug Resistance Assays in Leukemia and Lymphoma (eds.). Reading: Harwood, pp. 183-188.

5. Gillen D, **Emerson S**: Designing, monitoring, and analyzing group sequential trials using the RCTdesign package in R. (to appear in *Proceedings of the Fourth Seattle Symposium)*

d) Other non-refereed published scholarly publications

Contributed Abstracts and Presentations (not otherwise published):

1. Li KC, Elrahman MMMA, Kaude JV, Ros PR, Hardt NS, Drylie D, **Emerson SS**: Prostatic carcinoma: sonographic-clinical correlation. Annual Meeting, Association of University of Radiologists, 1989.

2. Kittelson JM, Barrett PJ, **Emerson SS**: Methods for comparing habitat preference curves. Western North American Region of the Biometric Society, 1990.

3. Ellis EA, Guy J, **Emerson S**, Hope GM: Morphometric analysis of remyelination in experimental optic neuritis. ARVO, 1990.

9. Patents and Other Intellectual Property

S+SeqTrial: An S-Plus module for the design, monitoring, and analysis of group sequential clinical trials. (C code core copyright Scott S. Emerson; S-Plus interface copyright Insightful, Inc.) also ported to R as RCTdesign

10. Funding History

10/1/2005 – 4/30/2009: Resuscitation Outcomes Consortium (NHLBI U01 HL077893: Emerson, PI from 7/1/2006 – 2/1/2009). Funds 70% S. Emerson salary to provide overall direction and statistical support to the data and statistical coordinating center for a network of centers conducting research on pre-hospital resuscitation strategies.

9/1/2005 – 6/30/2008: (NIH EB005829-01: Zhou, PI). Funds 10% S. Emerson salary to collaborate on research into statistical methods for sequential studies of diagnostic markers and nonparametric ROC curves.

4/1/2004 – 12/31/2005: Functional Genomics & HCV Associated Liver Disease (NIDA P30 DA015625: Katze, PI) Funds 20% S. Emerson salary to provide statistical support for research into molecular mechanisms in chronic HCV infection.

9/1/03 – 1/31/05: Ursodiol-Methotrexate for PBC (NIDDK DK92-15: Combes, PI), Data and Statistical Coordinating Center (Subcontract: Emerson, PI). Funded 15% S. Emerson salary to provide statistical support for multicenter Phase III clinical trial.

6/1/2003 – 5/31/2005: HCV Replication and Immune Response in HIV Coinfection (NIAID 5R01 AI49168: Gretch, PI) Funds 10% S. Emerson salary to provide statistical support.

9/30/01 – 8/31/04: Group Sequential Methods for Longitudinal Data (NHLBI R01 HL69719: Emerson, PI; $100,000 annual budget) Methodologic research into group sequential methods for longitudinal and survival data.

1/1/98 – 12/31/99: Next Generation Software for Group Sequential Analysis (NIH 1R43 CA69992: Bruce, PI) Phase II SBIR funded 40% S. Emerson salary for research and development of software related to the design, monitoring, and analysis of group sequential clinical trials.

9/1/97 – 8/31/03: Ursodiol-Methotrexate for PBC (NIDDK DK92-15: Combes, PI), Data and Statistical Coordinating Center (Subcontract: Carithers, PI). Funded 15% S. Emerson salary to provide statistical support for multicenter Phase III clinical trial.

5/1/97 – 10/1/98: Cardiovascular Health Study Coordinating Center (NHLBI: Kronmal, PI) Funded S. Emerson salary for statistical support for large multicenter observational study.

1/1/96 – 6/30/96: Next Generation Software for Group Sequential Analysis (NIH 1R43 CA69992: Bruce, PI) Phase I SBIR funded 25% S. Emerson salary for research and development of software related to the design, monitoring, and analysis of group sequential clinical trials.

6/1/95 – 12/31/96: Statistical Methods for Medical Studies (NIH P01 CA53996: Prentice, PI) Funded 5% S. Emerson salary for methodological research into group sequential trials.

6/1/95 – 5/1/97: Women's Health Initiative Clinical Coordinating Center (NIH N01 WH-2-2110: Prentice, PI) Funded 50% S. Emerson salary for statistical support for large Phase III prevention trial.

1/1/95 – 12/31/96: Teratogenic Effects on Fetal Rats of Extremely Low Frequency Magnetic Fields (Auckland Medical Research Council grant: G. Dawson, PI). Funded 5% S. Emerson effort as statistical consultant.

5/1/93 - 4/30/97: Depletion and Chemoprevention of Colon Cancer (NCI R01CA59024: Meyskens, PI). Subcontract for data management and statistical analysis (Emerson, PI; $12,000 annual budget).

1/1/91 – 12/31/95: Group Sequential Methods in Clinical Trials (NCI R29CA53449: Emerson, PI; $78,000 annual budget). Methodologic research into statistical techniques useful in group sequential clinical trials.

7/1/90 - 4/30/92: Colon Cancer Prevention Program Project (NCI CA41108: Alberts, PI), Biometry Core (McGee, Project Director; $205,317 annual budget). Funded 15% S. Emerson salary to work on Phase I-III clinical trials of colon cancer preventive agents.

12/15/89 - 12/31/91: Center Core Support Grant (NCI CA23074: Salmon, PI), Cancer Prevention and Control Shared Resource (Emerson, Project Director; $37,576 annual budget). Statistical consulting re cancer prevention and control.

11. Public Health Practice Activities

None

12. Conferences and Symposiums

Invited Presentations at Professional Meetings:

1. **Emerson SS**, Banks P: Estimation of secondary outcomes following a group sequential trial. Invited paper, ENAR Conference, Cincinnati, Ohio, March 1992.

2. **Emerson SS**: Issues in monitoring factorial designs. Invited paper, Joint Statistical Meeting, Boston Massachusetts, August 1992.

3. Gerner E, Hixson L, **Emerson S**, Shassetz R: Factors affecting the measurement of ODC activity and polyamine contents in colorectal tissues. Invited paper, Meeting of the American Society of Preventive Oncology, Tucson, Arizona, March 1993.

4. **Emerson SS**, Banks PLC: The application of group sequential estimation techniques to the results of unplanned interim analyses. Invited paper, Conference on the Interface of Computing and Statistics, San Diego, California, April 1993.

5. **Emerson SS**: Stopping a clinical trial early because of toxicity: A case study examined from different points of view. Invited panelist, Joint Statistical Meetings, San Francisco, California, August 1993.

6. **Emerson SS**: Selection of a group sequential design for monitoring clinical trials. Invited paper, Annual Meeting of the Drug Information Association, Washington, D.C., June 1994.

7. **Emerson SS**, Ritchie JM: Analyzing colon labeling data with a nonlinear random effects model. Invited paper, Joint Statistical Meetings, Toronto, Ontario, August 1994.

8. Freedman LS, **Emerson SS**: Design considerations for polyp prevention trials - with applications to the NCI Polyp Trial. Invited paper, Joint Statistical Meetings, Toronto, Ontario, August 1994.

9. **Emerson SS**, Durazo-Arvizu R: Estimation of Survivor Functions Following Group Sequential Testing. Invited paper, Meeting of the Statistical Society of Canada, Montreal, Canada, 1995.

10. **Emerson SS**: Using sensitivity analyses for early stopping of clinical trials based on secondary outcomes. Invited paper, Schering-Plough Workshop on Clinical Trials, Boston, Massachusetts, May 1996.

11. **Emerson SS**: DSMB membership and nonfinancial conflicts of interest. Invited paper, ENAR Annual Meeting, Pittsburgh, Pennsylvania, 1998.

12. **Emerson SS**, Kittelson JM, Gillen DL. On the use of stochastic curtailment in group sequential clinical trial design. 15th Annual Merck-Temple Conference.

13. Emerson SC, Rudser KD, **Emerson SS.** Exploring the benefits of adaptive sequential designs in time-to-event endpoint settings. (International Statistical Institute Meeting, Durban, South Africa, 2009)

Invited Seminars:

14. Design and interpretation of group sequential trials, University of Florida, Department of Statistics, January 1988.

15. Design and interpretation of group sequential trials, Ohio State University, Department of Statistics, February 1988.

16. Design and interpretation of group sequential trials, University of Wisconsin, Department of Statistics, February 1988.

17. Design and interpretation of group sequential trials, University of North Carolina, Department of Biostatistics, February 1988.

18. Parameter estimation following group sequential hypothesis tests, Harvard University, Department of Biostatistics, February 1989.

19. Parameter estimation following group sequential hypothesis tests, Mayo Clinic, Biostatistics Section, April 1989.

20. Parameter estimation following group sequential hypothesis tests, University of Arizona, Arizona Cancer Center, June 1989.

21. Interim analyses in clinical trials, University of Miami, Department of Epidemiology and Public Health, July 1989.

22. Interpreting results of group sequential trials, University of Michigan, Department of Biostatistics, October 1990.

23. Design and analysis of studies to reduce the incidence of colon polyps, Biometry Branch, Division of Cancer Prevention and Control, National Cancer Institute, February 1992.

24. Stopping a clinical trial very early due to unexpected toxicities, Bowman Gray School of Medicine, Department of Public Health Sciences, June 1994.

25. Analyzing colon crypt labeling data with a nonlinear random effects model, Clinical Division, Fred Hutchinson Cancer Research Center, Clinical Division, September 1994.

26. Stopping a clinical trial very early due to unexpected toxicities, University of Washington, Department of Biostatistics, September 1994.

27. A unified family of group sequential designs, University of Texas El Paso, Biostatistics Laboratory, February 1997.

28. Issues in nonparametric Bayesian analysis of clinical trials, University of Colorado Health Sciences, April, 2002.

29. Issues in nonparametric Bayesian analysis of clinical trials, University of Arizona, Mathematics, February, 2003.

30. Issues in nonparametric Bayesian analysis of clinical trials, Stanford University, Biostatistics, February, 2003.

31. Issues in nonparametric Bayesian analysis of clinical trials, NIAID, December, 2003.

32. Issues in nonparametric Bayesian analysis of clinical trials, Oregon State University, February, 2004.

33. Issues in nonparametric Bayesian analysis of clinical trials, Oregon State University, February, 2004.

34. On the use of stochastic curtailment in group sequential designs. University of Texas Southwestern, December, 2006.

35. Adaptive Clinical Trial Design. MMRI Klimt Lecture, Johns Hopkins Univesity, March 2007.

13. University Service

University of Arizona
Chair, Department of Statistics Consulting Committee, 1991-94
Member, Department of Statistics Computing Committee, 1991-95
Graduate Program Advisor, Department of Statistics, 1992-94
Member, Department of Statistics Academic Program Review Committee, 1991
Member, University Committee for the Re-organization of Statistics, 1995

University of Florida
Member, Biostatistics Curriculum Committee, 1988-89
Member, Search Committee for Division of Biostatistics faculty, 1989
Member, Clinical Research Center Advisory Committee, 1988-89
Member, Search Committee for Director of Biostatistics, 1989

University of Washington
Teacher/Mentor, Robert Wood Johnson Clinical Scholars Program
Member, Biostatistics Curriculum and Teaching Evaluation Committee (EPTEC), 1995-2008, 2010-present
Chair, First Year Theory Exam Committee, 1996, 2010

Computer Policy Committee, 1995-2002, Chair 1997-202
Member, Second Year Applied Exam Committee, 1997, 1998, 1999 (Chair), 2011
Chair, Core Curriculum Commitee, 1999-2002
Member, Second Year Theory Exam Committee, 2002, 2004
Graduate Program Coordinator, 2002-2005
Chair, Faculty Promotional Review Committee 1999, 2010, 2011
Faculty Council 2002-2005
Faculty Senate 2011-2012

14. Professionally-Related Community Service

Volunteer teacher of math, science and probability for 1 hour per week to 2nd through 5th graders in Tucson Unified School District, 1990-1995.
Consultant to Pima County Public Defenders Office in case regarding potential ethnic discrimination in jury selection process, 1994-95.
Lectures on clinical trials to 8th grade math classes at Eckstein Middle School, 1997.
Volunteer teacher of AP Statistics, Roosevelt High School, Seattle School District, 2001-2002.

15. Other Pertinent Information As Needed

Research Interests

Clinical trials, sequential testing, survival analysis, categorical data, nonparametric Bayesian statistics, classification and regression trees, statistical consulting, computer intensive methods.

16. Teaching History

a) Formal Courses

University of Virginia
Math 112: Introduction to Statistics: Evening class in introductory statistics for post-baccalaureate students. (3 sem hr)
Taught: Spr 1984 (15 students).

University of Florida
Stat 677: Advanced Biostatistics: Second semester of year long sequence in biostatistics for statistics graduate students (3 sem hr)
Taught: Sum, 1989 (8 students).

University of Arizona
Stat 565: Statistics for Medical Sciences: First semester introductory statistics for nonmajor graduate students. (3 sem hr).
Taught: Fall 1990 (35 students), Spr 1992 (42 students).

Stat 275: Statistics Methods for Management: Introductory statistics for undergraduate pre-business majors. (3 sem hr).
Taught: Spr 1991 (250 students).

Stat 566: Theory of Statistics: Two semester sequence in mathematical statistics for senior undergraduate math majors (first semester only) and statistics graduate students. (3-3 sem hr).
Taught: Fall 1992 (25 ugrad students; 12 grad students); Spr 1993 (12 grad students); Fall 1994 (27 ugrad students; 10 grad students); Spr 1995 (10 grad students).

Stat 596: Seminar - Theory of Estimation: Measure theoretic level statistical theory for advanced graduate students in statistics and applied math. (3 sem hr).
Taught: Spr 1992 (5 students).

Stat 596: Data Analysis Workshop: Workshop in applied data analysis for graduate students in statistics and applied math. (1 sem hr)
Taught: Fall 1992 (18 students); Spr 1993 (18 students); Fall 1994 (15 students).

Stat 677: Statistical Methods for Survival Analysis: Advanced survival analysis for statistics graduate students (3 sem hr)
Taught: Fall 1993 (10 students).

Stat 641: Statistical Consulting: Experience in statistical consulting on real problems for statistics graduate students (3 sem hr)
Taught: Spr 1993 (8 students); Spr 1994 (5 students).

University of Washington

BIOST/STAT 111: Seminars in Applied Stat: Lectures in applied statistics as a survey course for undergraduate nonmajors (1qtr hr)
Taught: Spr 1996 (33 students); Spr 1997 (64 students).

BIOST 512: Medical Biometry II: Applied regression analysis for nonmajor graduate students (4 qtr hr)
Taught: Win 1996 (76 students); Win 1997 (102 students); Win 1998 (57 students); Win 1999 (59 students); Win 2000 (60 students).

STAT 512: Mathematical Statistics I: Theory of mathematical statistics for first year graduate students in statistics, biostatistics, and quantitative ecology (4 qtr hr)
Taught: Fall 2003 (45 students).

STAT 513: Mathematical Statistics II: Theory of mathematical statistics for first year graduate students in statistics, biostatistics, and quantitative ecology (4 qtr hr)
Taught: Win 2004 (42 students).

BIOST 514: Biostatistics I: Introductory applied statistics for biostatistics graduate students (4 qtr hr)
Taught: Fall 1999 (21 students); Fall 2000 (19 students); Fall 2005 (12 students concurrent with Biost 517); Fall 2006 (12 students concurrent with Biost 517); Fall 2007 (14 students

concurrent with Biost 517); Fall 2009 (21 students concurrent with Biost 517); Fall 2010 (12 students concurrent with Biost 517); Fall 2011 (14 students concurrent with Biost 517)

BIOST 515: Biostatistics II: Introductory applied statistics for biostatistics graduate students (4 qtr hr)
Taught: Win 2006 (12 students concurrent with Biost 518); Win 2007 (12 students concurrent with Biost 518); Win 2008 (14 students concurrent with Biost 518).

BIOST 517: Applied Biostatistics I: Introductory applied statistics for nonmajor graduate students (4 qtr hr)
Taught: Fall 2001 (80 students); Fall 2002 (79 students); Fall 2005 (60 students); Fall 2006 (56 students); Fall 2007 (51 students), Fall 2009 (86 students), Fall 2010 (93 students); Fall 2011 (91 students)

BIOST 518: Applied Biostatistics II: Second quarter of introductory applied statistics for nonmajor graduate students (4 qtr hr)
Taught: Win 2002 (70 students); Win 2003 (61 students); Win 2006 (52 students), Win 2007 (46 students), Win 2008 (47 students).

BIOST 524: Design of Medical Studies: Issues in the design of clinical trials for graduate students in biostatistics and other public health disciplines (3 qtr hr)
Taught: Spr 2000 (24 students), Spr 2010 (16 students), Spr 2011 (18 students, cotaught).

BIOST/STAT 533: Theory of Linear Models: Theory underlying linear regression and ANOVA for biostatistics and statistics graduate students (3 qtr hr)
Taught: Spr 1999 (13 students), Spr 2009 (17 students).

BIOST/STAT 570: Advanced Applied Linear Models: Statistical methodology for regression analysis of independent data taken by second year PhD students in biostatistics and statistics (3 qtr hr)
Taught: Fall 1996 (17 students); Fall 1997 (20 students); Fall 1998 (24 students).

BIOST/STAT 578: Special Topics - Data Analysis: Experience in applied data analysis and report writing for second year PhD students in biostatistics and statistics (1-2 qtr hr)
Taught: Spr 2000 (8 students); Fall 2003 (12 students).

BIOST/STAT 578: Special Topics – Introductory Data Analysis: Experience in applied data analysis and report writing for first year students in biostatistics and statistics (3 qtr hr)
Taught: Spr 2005 (13 students).

BIOST/STAT 578: Special Topics – Group Sequential Methods: Overview of group sequential clinical trials for advanced biostatistics graduate students (1 qtr hr)
Taught: Win 2000 (15 students).

BIOST/STAT 578: Special Topics – Statistical Refereeing: Experience in providing statistical review of manuscripts submitted for publication to applied journals (1 qtr hr)
Taught: Spr 2002 (13 students).

BIOST/STAT 578: Special Topics – Statistical Design of Clinical Trials: For advanced biostatistics graduate students (3 qtr hr)
Taught: Sum 2003 (12 students).

BIOST/STAT 578: Special Topics – Introduction to R: For advanced biostatistics graduate students (1 qtr hr)
Taught: Aut 2010 (9 students).

BIOST/STAT 579: Data Analysis and Report Writing: Experience in applied data analysis and report writing for second year PhD students in biostatistics and statistics (1-2 qtr hr)
Taught: Fall 2011 (21 students).

STAT 582: Advanced Theory of Statistical Inference: Advanced theory at a measure theoretic level for second year PhD students in Statistics and biostatistics.
Taught: Win 2012 (22 students).

BIOST/STAT 590: Statistical consulting: Experience in providing real statistical consultation for advanced biostatistics graduate students (3 qtr hr)
Taught: Fall 2001 (8 students); Spr 2002 (8 students), Fall 2008 (8 students), Spr 2012 (8 students)

GEN ST 197: Freshman Seminar - Expanding Medical Knowledge: Issues in Clinical Experimentation: Informal freshman seminar providing survey of issues in medical study design (1 qtr hr)
Taught: 15-17 freshmen taught in each of Fall 1995; Spr 1996; Fall 1996; Win 1997; Spr 1997; Fall 1997; Win 1998; Fall 1998; Win 1999; Fall 1999; Win 2000.

b) Other Teaching

University of Arizona
College of Medicine Enrichment Elective: Introduction to Clinical Trials: Informal seminar giving a brief overview of clinical trial design and interpretation. Meeting 1 hour/week for 6 weeks, non-credit. Enrollment: 4 first and second year medical students. Taught: Spr 1990.

University of Washington

Epidemiology and Biostatisics: Applied Regression Analysis: Overview of regression analysis techniques. Meeting 2 hours/day for 5 days. Sponosored by Veteran's Administration. Enrollment: 50 medical researchers. Taught (and videotaped): Sum 2003.

Distance Learning- Group Sequential Clinical Trials: Pilot course for distance learning program in collaboration with 6 pharmaceutical companies. Lectures on CD, web-streaming; interactive sessions via teleconferencing. Developed and taught: 1998-1999.

Short Courses

Design, Monitoring, and Analysis of Group Sequential Clinical Trials: One to three day short courses on clinical trial design illustrated with S+Seqtrial.

Insightful Corporation, Princeton NJ (Jun 1999), Washington DC (Mar 2000), London UK (Jun 2000), Basel Switz (Jun 2000), Princeton NJ (Nov 2000),Basel Switz (Feb 2003)
University of Reading, Reading UK (Jul-Aug 1999)
Australasian Region of IBC, Hobart Australia (Dec 1999)
Lilly, Indianapolis IN (2000)
ICOS Corporation, Bothell WA (Jul 2000)
FDA, Rockville MD (Sep 2000)
Statistics Collaborative, Canaan Valley WV (Jan 2001)
SF Bay Area Chapter of ASA, Palo Alto CA (Jun 2001)
Puget Sound Chapter of ASA, Seattle WA (Aug 2001)
Joint Statistical Meetings, Atlanta GA (2001), New York NY (2002), San Francisco CA (2003)
Fourth Seattle Symposium, Seattle WA (2010)

Longitudinal Data Analysis: Half day continuing medical education on issues related to analyses of longitudinal data.

American Society of Nephrology, San Francisco CA (Oct 2001)

Data Monitoring Committees: One day short courses on issues related to monitoring clinical trials (co-taught with Tom Fleming).

Axioresearch, Berkeley CA (Mar 2003)

Advanced Topics in Survival Analysis: One day short course on issues related to analysis of survival data in the presence of nonproportional hazards.

Southern California Chapter of ASA, Long Beach CA (May 2004)

Genetic Data in Clinical Trials: Two and one-half day short course on the use of genetics data in clinical trials.

Cheju National University, Republic of Korea (Aug 2006)

Introduction to Clinical Trials: Two day short course to FDA medical officers and biostatisticians.

CBER, FDA, Rockville MD (Mar 2009, Oct 2009)

Adaptive Randomization in Clinical Trials: Invited half day short course.

ENAR Annual Meeting, New Orleans LA (Mar 2010)

Adaptive Clinical Trials:.
CDRH, FDA, Silver Spring MD (Nov 2010, one-day)
WNAR Annual Meeting, San Luis Obispo CA (Jun 2011)
FDA-Industry Workshop, Washington, DC (Sep 2011, half-day)

Missing Data in Clinical Trials:.
CBER, FDA, Silver Spring MD (One day short course to FDA biostatisticians, Apr 2011)
Association for Research in Vision and Ophthalmology / Society of Clinical Trials (Jointly sponsored 1 hour webinar, Nov 2011)
Society of Clinical Trials, 2012 Annual Meeting (Invited half day short course taught jointly with Jim Neaton, May 2012)

Course Development

University of Arizona

Data Analysis Workshop: 1 credit hour workshop to be offered each semester for graduate students in Statistics. Each week students analyze real data sets and informally discuss the problems that arise during that analysis. Class meets 2 hours per week, and students can earn up to 6 credits by repeated enrollment. First offered Fall, 1992.

Statistical Consulting: 3 credit hour course on Statistical consulting. Students consult with real clients under faculty supervision. 1 hour/week lecture on topics in statistical consulting. First offered Spring, 1993.

University of Washington

Applied Biostatistics (BIOST 517-518): Two quarter sequence in introductory biostatistics for nonmajor graduate students. First offered 2001-2002.

c) Independent Study

Not applicable

16. Advising and Formal Mentoring

a) PhD Dissertations, chair

University of Arizona

Justine Ritchie, Applied Mathematics, Ph.D., 1994, "Methods for Statistical Analysis of colonic crypt labeling".
Ramón Durazo, Applied Mathematics, Ph.D., 1994, "Adjustment of Bias in Survival Estimates Following Group Sequential Testing".
John Kittelson, Statistics, Ph.D., 1996: "The design of group sequential trials."

University of Washington

Daniel Gillen, Biostatistics, Ph.D., 2003, "The Use of Weighted Logrank Statistics in Group Sequential Trials with Nonproportional Hazards".
Martha Nason, Biostatistics, Ph.D., 2003, "Variable Importance in Tree-based Models". (co-advised with Michael LeBlanc)
Kyle Rudser, Biostatistics, Ph.D., 2007, "Variable Importance in Predictive Models: Separating Borrowing Information and Forming Contrasts".
Bart Burington, Biostatistics, Ph.D., 2009 "Flexible bootstrap monitoring of group sequential trials with longitudinal response data"
Siobhan Everson-Stewart, Ph.D., 2010 "Non-inferiority clinical trials: Bio-creep and a flexible margin approach for addressing non-constancy"
Abby Shoben, Ph.D., 2010 "Information growth in longitudinal clinical trials"
Sean Devlin, Ph.D., 2011 "Nonparametric ROC Curve Regression"
Greg Levin, Ph.D., 2012 "An Evaluation of Adaptive Clinical Trial Designs with Pre-specified Rules for Modifying the Sampling Plan"

b) Masters Theses, chair

University of Washington

Shengli Shi, Biostatistics, M.S., 2003. "Estimation Following Self-Designing Clinical Trial"
Mose Andre, Biostatistics, M.S., 2011 "Modelscans: A Tool for Visualizing Predictive Model Structure"
Eric Meier, Biostatistics, M.S., 2012 "A Sensitivity Analysis for Clinical Trials with Informatively Censored Survival Endpoints"

c) Mentored Scientists and Postdocs

Kyle Rudser, Ph.D. (2007 – 2008)

d) MS and PhD committees in non chair role

University of Arizona

Marcel Nzeukou, Agricultural Economics, Masters Examination Committee
Craig Abbey, Applied Mathematics, Ph.D. Preliminary Examination Committee
David Rauschenberg, Applied Mathematics, Ph.D. Final Examination committee
Jean Merilan, Statistics, Ph.D. Preliminary Examination Committee

University of Washington

Debashis Ghosh, Biostatistics, Ph.D., 1999.
Annamaria Kausz, Epidemiology, M.S., 1998.
Karen Lockhead, Epidemiology, M.S., 1998.
Craig Wang, Epidemiology, M.S., 1999.
Richard Wang, Biostatistics, M.S., 2003.
Shelley Tworoger, Epidemiology, Ph.D., 2003.
Kenneth Adams, Epidemiology, Ph.D., 2003.
Hao Liu, Biostatistics, Ph.D., 2004
Andy Bogart, Biostatistics, M.S., 2005.
David Coblentz, Biostatistics, M.S., 2007

Judy Zhong, Biostatistics, Ph.D. 2008
Scott Payseur Economics, Ph.D 2008, GSR
Joseph Koopmeiner Biostatistics, Ph.D. 2009
Andrea Burnett-Hartman Epidemiology, Ph.D. 2010, GSR
Maggie Au, Biostatistics, M.S., 2009
Erin Gabriel, Ph.D. 2012 (through general exam only))

e) Other Mentoring (Undergraduate Research, Medical School ISMS Projects, etc.)

University of Washington

Diane Bui, Undergraduate research assistant, 1996.
Peter Carney, Undergraduate research assistant 2002-2003.
Mose Andre, Undergraduate research assistant 2003-2005.
Joshua Rapkin, Undergraduate research assistant 2004-2005.

f) Academic Advising

University of Washington, Department of Biostatistics

Julie Stoner, Katherine Guthrie, Mark Giganti, Mose Andre, Yuying Jin, Amy Laird, Brett Hanscom, Megan Smith, William Cumberland, Kevin Joyce