

Sally Hunsberger

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Education

- 1990 PHD Biostatistics, Medical College of Virginia, VCU, Richmond, Virginia. Ph.D. dissertation "Semiparametric Regression in Likelihood Based Models."
- 1986 B.A. Mathematics and Biology, Goshen College, Goshen, Indiana

Honors & awards

- 1997 NIH Office of Equal Opportunity award for guiding the summer project of a stay in school student
- 1994 NIH Merit Award for exceptional performance of statistical collaboration on clinical research programs in NHLBI.
- 1991 The Eastern North American Region Biometric Society Student Prize Award for best paper.
- 1986-1990 Medical College of Virginia, VCU, School of Graduate Studies Fellowship
- 1984,1985 Academic All-American NAIA Tennis award

Professional Experience

- 2013- Mathematical Statistician, Biometrics Research Branch, National Allergy and Infectious Disease Institute. Duties include: Design of studies and statistical analyzes for the Laboratory of clinical Infectious Diseases and La Red. La Red is a multi-site collaboration between NIAID and Mexico Ministry of Health designed to promote research on emerging infectious diseases.
- 2001- Member of Data Safety and Monitoring Committee for the Pediatric Heart Network, sponsored by the National Heart Lung and Blood Institute.
- 1999-2013 Mathematical Statistician, Biometrics Research Branch, National Cancer Institute. Duties included: Data Safety and Monitoring Committee member for the Children's Oncology Group(COG), National Surgical Adjuvant Breast and Bowel Project (NSABP), New Approaches to Neuroblastoma Treatment consortium (NANT) and, Pediatric Brain Tumor consortium (PBTC). Review Phase I, II and III cancer trial protocols. Develop Statistical procedures for Cancer research.
- 2006-2013 Member of the Data Safety and Monitoring Committee for the Gene and Cell therapy sponsored by the National Heart Lung and Blood Institute.
- 1991-1999 Mathematical Statistician, Office of Biostatistics. National Heart, Lung and Blood Institute. Duties included: Consulting with intramural investigators at the NIH clinical

center, performing statistical methodological research, participating in the design and analysis of large national multicentered clinical trials, and participating in DSMB discussions. Trials have worked on:

Diet Intervention Study In Children (DISC)-randomized trial of 664 children with elevated LDL-cholesterol for prevention of cardiovascular disease.

Digitalis Investigation Group (DIG)- collaborative international, double- blind, randomized controlled clinical trial of 6000 patients with heart failure designed to assess the effect of digoxin on mortality, morbidity and quality of life.

Enhanced Recovery in Coronary Heart Disease (ENRICHED)- randomized clinical trial in post MI socially isolated and depressed patients to determine the efficacy of social support for survival.

Obesity prevention in Native American Indians (Pathways)-9 year school based study focused on the primary prevention of obesity in pre-adolescent Native Americans.

Postmenopausal Estrogen/Progestin Intervention Trial (PEPI)- five arm, double blind, randomized clinical trial with 3 year follow-up looking at the effects of hormone replacement therapies on heart disease risk factors and osteoporosis.

Treatment of Raynaud's Syndrome (RTS)- randomized clinical trial to determine the efficacy of temperature biofeedback treatment and pharmacological treatments for Raynauds syndrome.

- 1998 One year sabbatical at St. Johns Medical college, Bangalore, India as a Biostatistics consultant.
- 1990 Medical College of Virginia, VCU. Instructor "Statistical Methods" course.
- 1986-1990 Medical College of Virginia, VCU, Graduate Research Assistant.
- 1987 Medical College of Virginia, VCU, Student Director Biostatistical Consulting Laboratory.
- 1985 Lovelace Biomedical and Environmental Research Institute, Summer Intern.

Professional Activites

Member American Statistical Association and Biometric Society.

Human Rights Committee member for the American statistical Association.

Program Chair American Statistical Association meetings.

Organized Invited Session for ENAR meetings.

Program chair for Biostatistics and Public Health for the Washington Statistical Society.

Referee for: *Biometrics*, *Controlled Clinical Trials*, *Epidemiology*, *Journal of the National Cancer Institute*, *Journal of Clinical Oncology*, *Statistics in Medicine*, *Technometrics* and

Article for Book "Statistics for Quality: Dedicated to DON OWEN", editors: Subir Ghosh, William R. Schucany, and William B. Smith.

Invited Presentations

- 2013 Zhejiang International Symposium on the Progress of Image Guided Radiation Therapy Conference: "Considerations of Clinical Trial Designs and Modern Image Guided Radiation Therapy".
- 2013 Joint Statistical Meetings, "Study Design Issues and Analysis Analysis of Error-prone Time to Event Data Using Progression Free Survival as an Example".

- 2013 International Chinese Statistical Meetings, “Approaches to retrospective sampling for longitudinal transition regression model”.
- 2012 San Antonio Breast Cancer Symposium, “When Should Studies be Randomized”.
- 2011 Virginia Commonwealth University, “A Finite Mixture Survival Model to Characterize Risk Groups of Neuroblastoma”.
- 2011 Global Breast Cancer Conference, Seoul South Korea, “Designs for Breast Cancer Studies in the Face of Changing Drug Development Issues” and “Seamless Phase II/III Designs for Breast Cancer Studies”.
- 2007 Annual Meeting of Korean Cancer Association, Seoul South Korea, “Study design considerations for clinical trials of targeted agents” and “Progression-Free Survival in Unblinded Randomized Trials: A Proposal”.
- 2006 Joint Statistical Meetings, “Testing Logistic Regression Coefficients with Clustered Data and Few Positive Outcomes”.
- 2005 Speaker in Education Session at ASCO, “Ethical and Clinical Dilemmas Resulting from the Early Closure of Recent Clinical Trials in Breast Cancer”.
- 2005 Discussant in Pediatric Oral Presentation session at ASCO.
- 1999 Virginia Commonwealth University, Medical College of Virginia, “A Test of Additivity in Semiparametric Regression using Kernel Smoothing.”
- 1996 National Cancer Institute, “A Test of Additivity in Semiparametric Regression using Kernel Smoothing.”
- 1996 Joint Statistical Meetings, “Imputation Strategies for Missing Data in a School Based Multicenter Study of American Indian Children: The Pathways Study.”
- 1993 Lecture Series sponsored by Division of Computer Research and Technology, National Institutes of Health, “Designing Research Experiments an Iterative, Collaborative Process.”

Publications

S Hunsberger, P S Albert, and M Thoma. Approaches to retrospective sampling for longitudinal transition regression model. *Statistics and It's Interface*, 2013.

S Hunsberger. *Phase II/III Designs Chapter 12 in Handbook of Statistics in Clinical Oncology, Third Edition*. CRC press, 2012.

N Takebe, S Hunsberger, and SX Yang. Expression of gli1 in the hedgehog signaling pathway and breast cancer recurrence. *Chinese Journal of Cancer Research*, 24:257–258, 2012.

S Gupta, S Hunsberger, S Boerner, R Roydsand P Ivy, and P LoRusso. Meta-analysis of the relationship between dose and benefit in phase I targeted agent trials. *Journal of the National Cancer Institute*, 104:1860–1866, 2012.

MP Fay and S Hunsberger. *Practical issues on using weighted logrank tests with interval censored events in clinical trials, Chapter 13 in Interval Censored Time-to-Event Data: Methods and Applications*. Chapman and Hall/CRC, 2012.

M Wang, J Dignam, QE Zhang, JF DeGroot, MP Mehta, and S Hunsberger. Integrated phase II/III clinical trials in oncology; a case study. *Clinical Trials*, 9:741–747, 2012.

- PM LoRusso, S Boerner, and S Hunsberger. Clinical development of vascular disrupting agents: What lessons can we learn from asa404? *Journal of clinical Oncology*, 29:2952–2955, 2011.
- M Smith, M Devidas, K Wheatley, RB Lock, and S Hunsberger. *Strategies for new agent development and clinical trial considerations Chapter 8 in Childhood Leukemia*. Springer-Verlag, 2011.
- S Hunsberger, PS Albert, and L Dodd. Analysis of progression-free survival data using a discrete time survival model that incorporates measurements with and without diagnostic error. *Clinical Trials*, 7:634–642, 2010.
- S Hunsberger, Y Zhao, and R Simon. A comparison of phase II study strategies. *Clinical Cancer Research*, 15:5950–5955, 2010.
- S Hunsberger, PS Albert, and WB London. A finite mixture survival model to characterize risk groups of neuroblastoma. *Statistics in Medicine*, 28:1301–1314, 2009.
- LM McShane, S Hunsberger, and AA Adjei. Effective incorporation of biomarkers into phase II trials. *Clinical Cancer Research*, 15:1898–1905, 2009.
- R Ballard-Barbash, S Hunsberger, MH Alciati MH, SN Blair, PJ Goodwin, A McTier-nan, R Wing, and A Schatzkin. Physical activity, weight control and breast cancer risk and survival: clinical trial rationale and design considerations. *Journal of the National Cancer Institute*, 101:630–643, 2009.
- EL Korn S Hunsberger, B Freidlin, MA Smith, and JS Abrams. Comments on 'maintaining confidentiality of interim data to enhance trial integrity and credibility by TR Fleming et al. *Clinical Trials*, 5:364–365, 2008.
- S Hunsberger, B Freidlin, and MA Smith. Complexities in interpretation of osteosarcoma clinical trial results. *Journal of Clinical Oncology*, 26:3103–3104, 2008.
- PC Nathan, T Whitcomb, PL Wolters, SM Steinberg, FM Balis, P Brouwers, S Hunsberger, J Feusner, H Sather, J Miser, LF Odom, D Poplack, G Reaman, and WA Bleyer. Very high-dose methotrexate (33.6 g/m²) as central nervous system preventive therapy for childhood acute lymphoblastic leukemia: results of national cancer institute/children's cancer group trials ccg-191p, ccg-134p and ccg-144p. *Leukemia and Lymphoma*, 47:2488–2504, 2006.
- MA Proschan and SA Hunsberger. Combining treatment selection and definitive testing. *Biometrical Journal*, 48:690–692, 2006.
- EL Korn, LV Rubinstein, SA Hunsberger, JM Pluda, E Eisenhauer, and SG Arbuck. *Clinical trial design for cytostatic agents and agents directed at novel molecular targets In Strategies for Discovery and Clinical Testing of Novel Anticancer Agents*. Elsevier, 2005.
- P Albert and S Hunsberger. On analyzing circadian rhythm data using non-linear mixed models with harmonic terms. *Biometrics*, 61:1115–1120, 2005.

- EL Korn, LV Rubinstein, SA Hunsberger, JM Pluda, E Eisenhauer, and SG Arbuck. *Clinical trial design for cytostatic agents and agents directed at novel molecular targets In Strategies for Discovery and Clinical Testing of Novel Anticancer Agents*. Elsevier, 2005.
- LV Rubinstein, EL Korn, B Freidlin, SA Hunsberger, SP Ivy, and MA Smith. Randomized phase 2 design issues and a proposal for phase 2 screening trials. *Journal of Clinical Oncology*, 23:7199–7206, 2005.
- S Hunsberger, LV Rubinstein, J Dancey, and EL Korn. Dose escalation trial designs based on a molecularly targeted endpoint. *Statistics in Medicine*, 24:2171–2181, 2005.
- PS Albert, SA Hunsberger, and N Hu. Identifying multiple change points in heterogeneous binary data with an application to molecular genetics. *Biostatistics*, 5:515–529, 2004.
- E Lader, D Egan, S Hunsberger, R Garg, S Czajkowski, and F McSherry. The effect of digoxin on the quality of life in patients with heart failure. *Journal of Cardiac Failure*, 9:4–12, 2003.
- MA Proschan, Q Liu, and S Hunsberger. Practical midcourse sample size modification in clinical trials. *Controlled Clinical Trials*, 24:4–15, 2003.
- JF, Dorgan, SA Hunsberger, RP McMahon, PO Kwiterovich, RM Lauer, L Van Horn, NL Lasser, VJ Stevens, LA Friedman, JA Yanovski, SF Greenhut, DW Chandler, FA Franklin, BA Barton, DW Buckman, LG Snetselaar, BH Patterson, A Schatzkin, and PR Taylor. Diet and sex hormones in girls: Findings from a randomized controlled clinical trial. *Journal of the National Cancer Institute*, 95:132–141, 2003.
- S Hunsberger, PS Albert, DA Follmann, and E Suh. Parametric and semiparametric approaches to testing for seasonal trend in serial count data. *Biostatistics*, 3:289–298, 2002.
- B Thompson B, RG Jacob, M Frederick, NL Geller, and S Hunsberger. Innovative designs in behavioural trials. *Statistics in Medicine*, 21:2981–2989, 2002.
- EF Philbin, S Hunsberger, R Garg, E Lader, D Thadani, F McSherry, and MA Silver. Usefulness of clinical information to distinguish patients with normal from those with low ejection fractions in heart failure. *American Journal of Cardiology*, 89:1218, 2002.
- M Vaz, S Hunsberger, and B Diffey. Prediction equations for handgrip strength in healthy indian male and female subjects encompassing a wide age range. *Annals of Human Biology*, 29:131–141, 2002.
- S Hunsberger and D Follmann. A test of additivity in semiparametric regression using kernel smoothing. *Statistics in Medicine*, 20:1–19, 2001.
- J Moss, NA Avila, PM Barnes, RA Litzenberger, J Bechtle, PG Brooks CJ, Hedin, S Hunsberger, and AS Kristof. Prevalence and clinical characteristics of lymphangiomyomatosis (lam) in patients with tuberous sclerosis complex. *American Journal of Respiratory and Critical Care Medicine*, 164:669–671, 2002.

MA Proschan, RP, McMahon, JH Shih, SA Hunsberger, NL Geller, G Knatterud, and J Wittes. Sensitivity analysis using an imputation method for missing binary data in clinical trials. *Journal of Statistical Planning and Inference*, 96:155–165, 2001.

S Hunsberger, CE Davis, D Murray, and R Fabsitz. Imputation strategies for missing data in a school based multicenter study of american indian children: The pathways study. *Statistics in Medicine*, 20:305–316, 2001.

E Obarzanek, SY Kimm, BA Barton, L Van Horn, PO Kwiterovich, DG Simons-Morton, S Hunsberger NL Lasser, AM Robson, FA Franklin, RM Lauer VJ Stevens LA Friedman JF Dorgan, and MR Greenlick. Long-term safety and efficacy of a cholesterol-lowering diet in children: Seven-year results of the dietary intervention study in children(disc). *Pediatrics*, 107:256–264, 2001.

TG Lohman, B Caballero, JH Himes, CE Davis, D Stewart, L Houtkooper, SB Going, SA Hunsberger, JL Weber, R Reid, and L Stephenson. Estimation of body fat from anthropometry and bioelectrical impedance in native american children. *International Journal of Obesity*, 24:2–7, 2000.

J Mathew, S Hunsberger, J Fleg, F McSherry, W Williford, and S Yusuf. Incidence, predictive factors and prognostic significance of supraventricular tachyarrhythmias in congestive heart failure. *Chest*, 118:914–922, 2000.

DA Follmann, S Hunsberger, and PS Albert. Repeated binary regression when covariates are measured with error. *Biometrics*, 55:403–4–9, 1999.

C Davis, S Hunsberger, D Murray, R Fabsitz, J Himes, and L Stephenson. Design and statistical analysis for pathways. *American Journal of Clinical Nutrition*, 69:760S–763S, 1999.

T Lohman, B Caballero, J Himes, S Hunsberger, R Reid, and D Stewart. Body composition assessment in american indian children. *American Journal of Clinical Nutrition*, 69:760S–766S, 1999.

S Going, S Levin, J Harrell, D Stewart, L Kushi C Cornell, S Hunsberger, C Corbin, and J Sallis. Physical activity assessment in school-age american indian children in the pathways study. *American Journal of Clinical Nutrition*, 69:788S–795S, 1999.

B Thompson, N Geller, S Hunsberger M Fredrick R Hill, P Kaufmann RG Jacob, RR Freedman, EA Smith, FM Wigley, and L Bielory. Designing clinical trials when interventions require different treatment and followup methods: The raynauds treatment study. *Controlled Clinical Trials*, 20:52–63, 1999.

P Kwiterovich, BA Barton, R McMahon, E Obarzanek, S Hunsberger, D Simons-Morton, SYS Kimm, LA Friedman, N Lasser, A Robson, R Lauer, L Van Horn, V Stevens, S Gidding L Snetslaar, V Hartmuller, and F Franklin. Effects of dietary cholesterol and fat on ldl cholesterol during puberty: the dietary intervention study in children(disc). *Circulation*, 98:2526–2533, 1998.

PS Albert and S Hunsberger. Modeling repeated measures with monotonic ordinal responses and misclassification: With applications to studying maturation. *Journal of the American Statistical Association*, pages 1304–1312, 1997.

E Obarzanek, S Hunsberger, B Barton, F Franklin, V Hartmuller, S Kimm, P Kwiterovich, R Lauer, V Stevens, and L Van Horn. Safety of a fat-reduced diet in growing children: dietary intervention study in children(disc). *Pediatrics*, pages 51–59, 1997.

D Simons-Morton, S Hunsberger, L Van Horn, B Barton A Robson, R McMahon, L Muhonen amd P Kwiterovich, N Lasser, S Kimm, and M Greenlick. Diet and blood pressure relationships in children: Dietary intervention study in children. *Hypertension*, 29:930–936, 1997.

EG Toporoff, AF Simone, M Story, JH Himes, MP Snyder, M Dubray, B Holy Rock, and S Hunsberger. Do children eat what they say? validity of intended food choices among native american school children. *Obesity Research*, 5:87–92, 1997.

The Writing Group for the PEPI Trial. Effects of hormone therapy on bone mineral density in the spine and hip: Results from the postmenopausal estrogen/progestin intervention (pepi) trial. *Journal of the American Medical Association*, 6:1430–1442, 1996.

DF Lazarous, M Scheinowitz, M Shou, E Hodge, S Rajanayagam, S Hunsberger, WG Rbinson, JA Stiber, R Correa, and EF Unger. Effects of chronic systemic administration of basic fibroblast growth factor on collateral development in the canine heart. *Circulation*, pages 145–153, 1995.

MA Proschan and S Hunsberger. Extending studies based on conditional power. *Biometrics*, 51:1315–1324, 1995.

The Writing Group for the DISC Collaborative Research Group. Efficacy and safety of lowering dietary intake of fat and cholesterol in children with elevated low-density lipoprotein cholesterol: the dietary intervention study in children(disc). *Journal of the American Medical Association*, pages 1429–1435, 1995.

The Writing Group for the PEPI Trial (1995). Effects of estrogen or estrogen/progestin regimens on heart disease risk factors in postmenopausal women. *he Journal of the American Medical Association*, pages 199–206, 1995.

SA Hunsberger. Semiparametric regression in likelihood based models. *Journal of the American Statistical Association*, pages 1354–1365, 1994.

S Hunsberger, P Sorlie, and N Geller. Stochastic curtailing and conditional power in matched case–control studies. *Statistics in Medicine*, pages 663–670, 1994.

GC Mautner, SL Mautner, RO Cannon, SA Hunsberger, and WC Roberts. Clinical factors useful in predicting aortic valve structure in patients >40 years of age with isolated valvular stenosis. *American Journal of Cardiology*, 72:194–198, 1994.

MC Wu, SA Hunsberger, and D Zucker. Testing for differences in changes in the presence of censoring: Semiparametric versus parametric and nonparametric methods. *Statistics in Medicine*, pages 635–646, 1994.

ZA Abassi, J Tate, SA Hunsberger, H Klein, D Trachewsky, and HR Keiser. Pharmacokinetics of anf and urodilatin during c-anf receptor blockade and neutral endopeptidase inhibition. *American Journal of Physiology*, pages E870–E876, 1992.

SL Mautner, GC Mautner, SA Hunsberger, and WC Roberts. Comparison of composition of atherosclerotic plaques in saphenous vein used as aortocoronary bypass conduits with plaques in native coronary arteries in the same men. *The American Journal of Cardiology*, pages 1380–1387, 1992.

CW Armstrong CG Mayhall, KB Miller, HH Newsome, HJ Sugarman, HP Dalton GO Hall, and SA Hunsberger. Clinical predictors of infection of central venous catheters used for total parenteral nutrition. *Infection Control and Hospital Epidemiology*, 11:71–78, 1990.

MA Medinsky, JA Bond, and SA Hunsberger. A physiologically based model of 1-nitropyrene metabolism after inhalation or ingestion. *Health Physics*, 57:149–155, 1989.

MA Medinsky, JA Bond, SA Hunsberger, and JD Sun. Lung, liver, and kidney as potential target organs after exposure to 1-nitropyrene, as determined by the time course of covalently bound material. *Journal of Toxicological Environmental Health*, 23:445–454, 1989.

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