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Education:

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

Awards:

2022: NIH Director's Group Award for the contributions to the NIAID sponsored Covid-19 research efforts. The team led the effort in developing and implementing a COVID-19 observational vaccine study. This study will assess immunogenicity, durability, and severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infections in people who received an locally available COVID-19 initial vaccine or booster vaccine regimen at international sites.
2021: NIH Director's Award "For outstanding efforts in the pursuit of efficacious vaccines to prevent COVID-19" as part of the Advancing COVID-19 Vaccines: ACTIV and HHS Collaborations.
2021: NIH Director's Award for "Establishing and analyzing the first representative US serosurvey of SARS-CoV-2, leading to identification of 17 million undiagnosed cases of COVID-19 as of summer 2020" as a member of the COVID-19 Serosurvey Team.
2020/21: NCATS Director's Award in the Scientific/Medical category with the following citation: "In recognition for working together to rapidly create a trans-NIH serosurvey clinical research program in March 2020 to assess the extent of SARS-CoV-2 spread in the community."
2006: Goshen College Champions of Character Award for those who have gone on to exemplify and demonstrate the core values of Goshen College.
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-present: Mathematical Statistician, Biometrics Research Branch, National Institute of Allergy and Infectious Diseases. Duties include: executive secretary for the Division of AIDS (DAIDS) prevention and therapeutic. Protocol review for the Laboratory of Clinical Immunology and Microbiology (LCIM) and Laboratory of Infectious Disease (LID). Statistical design and analysis for LCIM and LID studies. LCIM study designs are typically for rare diseases and LID typically performs challenge studies. Scientific lead for the InVITE study which is a study to estimate antibody response to locally provided vaccines seven countries: Guinea, Indonesia, Liberia, Mali, Mexico, Democratic Republic of Congo, and Mongolia.

2001-present: Member of Data Safety and Monitoring Committee for the Pediatric Heart Network, sponsored by the National Heart Lung and Blood Institute.

2020-2022: Executive Secretary for the COVID-19 vaccine Data Safety Monitoring Board.

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.

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 Activities:

FDA Advisory committee member (beginning December 1, 2020) Antimicrobial Drugs Advisory Committee, temporary member for CEBER’s Cellular Tissue and Gene Therapies Advisory Committee, October 12, 2017, Gastro Intestinal Drug advisory committee (frequently), Oncologic Drugs Advisory committee, and the Bone, Reproductive and urologic Drugs Advisory committee.

Program committee member for Eastern North American Region statistical (ENAR) meetings 2021.

Editorial board Journal of Clinical Oncology 2019-2022.

Session Chair ENAR 2018.

Member American Statistical Association and Biometric Society Human Rights Committee member for the American Statistical Association (2009-2012).

Session Chair American Statistical Association meetings(2000).

Organized Invited Session spring ENAR meetings (1997).

Program chair for Biostatistics and Public Health for the Washington Statistical Society.(1993-1995).

Refereed for *Nature Medicine*, *American Journal of Epidemiology*, *Biometrics*, *Controlled Clinical Trials*, *Epidemiology*, *Journal of Applied Statistics*, *Journal of the National Cancer Institute*, *Journal of Clinical Oncology*, *Journal of Acquired Immune Deficiency Syndrome*, *Statistics in Medicine*, *Technometrics*, *Trials*, and Article for Book “Statistics for Quality: Dedicated to DON OWEN”, editors: Subir Ghosh, William R. Schucany, and William B. Smith.

Invited Presentations:

International Clinical Research Networks Forum – A Collaborative Approach for Pandemic Preparedness, 2022: “Development and Implementation of the InVITE Study”

Society for Clinical Trials, 2022: “COVID-19 Vaccine Data Safety and Monitoring Board (DSMB): Executive Secretary’s Experience”.

Cancer Research and Biostatistics, 2022: “Data Safety and Monitoring Board (DSMB) Experience Related to COVID-19 Trials”.

NIAID, DCR medical monitors, 2021: “Data Safety and Monitoring Board (DSMB) Experience Related to COVID-19 Trials”.

Joint Statistical meetings, August 2021: “Better estimation of variances for cluster data using U statistics”.

ENAR, 2021: “Pooling decisions in real life with India as an example”.

Patient-Centered Outcomes Research Institute, 2019: “Interim Analysis Discussion”.

International Collaboration for Research Methods Development in Oncology workshop in India, 2018: “How to Handle Missing Data” and “Odds Ratios, Risk Ratios and Logistic Regression Methods”.

International Collaboration for Research Methods Development in Oncology workshop in India, 2017: “How to Handle Missing Data”.

US-Georgia writing Workshop, 2016: “What you need to know about statistics”.

UHS-NIH Scientific Writing Workshop in Laos, 2015: “Overview of Study Designs” and “Writing the Results Section”.

Goshen College, 2014: “Simple Approaches to Analyzing Self-Controlled Case Series (SCCS) Data”.

ASCO International Clinical Trials workshop, Nepal, 2014: “Statistical Considerations in Clinical Trials”.

Zhejiang International Symposium on the Progresses of Image Guided Radiation Therapy Conference, 2013: “Considerations of Clinical Trial Designs and Modern Image Guided Radiation Therapy”.

Joint Statistical Meetings, August 2013: “Study Design Issues and Analysis Analysis of Error-prone Time to Event Data Using Progression Free Survival as an Example”.

San Antonio Breast Cancer Symposium, December 2012. “When Should Studies be Randomized”.

Virginia Commonwealth University, December 2011. “A Finite Mixture Survival Model to Characterize Risk Groups of Neuroblastoma”.

Global Breast Cancer Conference, Seoul South Korea, October 2011. “Designs for Breast Cancer Studies in the Face of Changing Drug Development Issues” and “Seamless Phase II/III Designs for Breast Cancer Studies”.

Annual Meeting of Korean Cancer Association, Seoul South Korea, June 2007. “Study design considerations for clinical trials of targeted agents” and “Progression-Free Survival in Unblinded Randomized Trials: A Proposal”.

Joint Statistical Meetings, August 2006. “Testing Logistic Regression Coefficients with Clustered Data and Few Positive Outcomes”.

Speaker in Education Session at ASCO May 2005: “Ethical and Clinical Dilemmas Resulting from the Early Closure of Recent Clinical Trials in Breast Cancer”.

Discussant in Pediatric Oral Presentation session at ASCO May 2005.

Virginia Commonwealth University, Medical College of Virginia 1999: “A Test of Additivity in Semiparametric Regression using Kernel Smoothing.”

National Cancer Institute 1996: “A Test of Additivity in Semiparametric Regression using Kernel Smoothing.”

Joint Statistical Meetings, Chicago 1996: “Imputation Strategies for Missing Data in a School Based Multicenter Study of American Indian Children: The Pathways Study.”

Lecture Series sponsored by Division of Computer Research and Technology, National Institutes of Health 1993: “Designing Research Experiments an Iterative, Collaborative Process.”

Publications

Hunsberger, S., Ellenberg, S.S., Joffe, S., Babiker, A., Fix, A., Griffin, M.R., Kalil, J., Levine, M.M., Makgoba, M.W., Moore, R.H. and Tsiatis, A.A., (2023). Monitoring Multiple US Government-Supported Covid-19 Vaccine Trials. *NEJM Evidence*, 2(3), p.EVIDctcs2200301.

del Carmen Guerra-de-Blas, P., Ortega-Villa, A.M., Ortiz-Hernández, A.A., Ramírez-Venegas, A., Moreno-Espinosa, S., Llamosas-Gallardo, B., Pérez-Patrigeon, S., Hunsberger, S., Magaña, M., Valdez-Vázquez, R. and Freimanis, L., 2023. Etiology, clinical characteristics, and risk factors associated with severe influenza-like illnesses in Mexican adults. *IJID regions*, 6, pp.152-158.

Sereti, I., Shaw-Saliba, K., Dodd, L. E., Dewar, R. L., Laverdure, S., Brown, S., ... Hunsberger, S. (2022). Design of an Observational Multi-country Cohort Study to Assess Immunogenicity of Multiple Vaccine Platforms (InVITE). *Plos one*, 17(9), e0273914.

Hunsberger, S., Long, L., Reese, S. E., Hong, G. H., Myles, I. A., Zerbe, C. S., ... Shih, J. H. (2022). Rank Correlation Inferences for Clustered Data With Small Sample Size. *Statistica Neerlandica*.

Desai, J. V., Urban, A., Swaim, D. Z., Colton, B., Kibathi, L. W., Ferrè, E. M., ... Freeman, A. F. (2022). Efficacy of Cochleated Amphotericin B in Mouse and Human Mucocutaneous Candidiasis. *Antimicrobial Agents and Chemotherapy*, 66(7), e00308-22.

Friedman-Klabanoff, D. J., Birkhold, M., Short, M. T., Wilson, T. R., Meneses, C. R., Lacsina, J. R., ... , Laurens, M. B. (2022). Safety and immunogenicity of AGS-v PLUS, a mosquito saliva peptide vaccine against arboviral diseases: A randomized, double-blind, placebo-controlled Phase 1 trial. *Ebiomedicine*, 86, 104375.

Chauvin, S. D., Price, S., Zou, J., Hunsberger, S., Brofferio, A., Matthews, H., ... Ravell, J. C. (2022). A Double-Blind, Placebo-Controlled, Crossover Study of Magnesium Supplementation in Patients with XMEN Disease. *Journal of Clinical Immunology*, 108-118.

Giurgea, Luca T., Adriana Cervantes-Medina, Kathie-Anne Walters, Kelsey Scherler, Alison Han, Lindsay M. Czajkowski, Holly Ann Baus et al. *Sex differences in influenza: the challenge study experience*. The Journal of infectious diseases 225, no. 4 (2022): 715-722.

Kalish, H., Klumpp-Thomas, C., Hunsberger, S., Baus, H. A., Fay, M. P., Siripong, N., ... Sadtler, K. (2021). Undiagnosed SARS-CoV-2 Seropositivity During the First Six Months of the COVID-19 Pandemic in the United States. *Science Translational Medicine*, July 7, 13(601).

Fay, M. P., Hunsberger, S., Follmann, D. (2021). Risk Heterogeneity and the Illusion of Waning Vaccine Efficacy. *Annals of internal medicine*.

Joffe, S., Babiker, A., Ellenberg, S. S., Fix, A., Griffin, M. R., Hunsberger, S., ... Whitley, R. (2021). Data and Safety Monitoring of COVID-19 Vaccine Clinical Trials. *The Journal of infectious diseases*.

Han, A., Czajkowski, L., Rosas, L. A., Cervantes-Medina, A., Xiao, Y., Gouzoulis, M., ... Memoli, M. J. (2021). Safety and Efficacy of CR6261 in an Influenza A H1N1 Healthy Human Challenge Model. *Clinical Infectious Diseases*. 73(11), e4260-e4268.

Belaunzarán-Zamudio, P. F., Mateja, A., Guerra-de-Blas, P. D. C., Rincón-León, H. A., Navarro-Fuentes, K., Ruiz-Hernández, E., ... Mexican Emerging Infectious Diseases Clinical Research Network (LaRed). (2021). Comparison of clinical characteristics of Zika and dengue symptomatic infections and other acute illnesses of unidentified origin in Mexico. *PLoS neglected tropical diseases*, 15(2), e0009133.

Hunsberger, S., Ortega-Villa, A. M., Powers III, J. H., León, H. A. R., Sosa, S. C., Hernández, E. R., ... and de Blas, P. D. C. G. (2020). Patterns of signs, symptoms, and laboratory values associated with Zika, dengue, and undefined acute illnesses in a dengue endemic region: Secondary analysis of a prospective cohort study in southern Mexico. *International Journal of Infectious Diseases*, 98, 241-248.

Dean, O., Anjum, S., Scott, T., Ham, L., Traino, K., Wang, J., ... Williamson, P. R. (2021). Quality of life of HIV-negative, previously healthy individuals following cryptococcal meningoencephalitis. *Scientific reports*, 11(1), 1-8.

Anjum, S., Dean, O., Kosa, P., Magone, M. T., King, K. A., Fitzgibbon, E., ... Williamson, P. (2021). Outcomes in Previously Healthy Cryptococcal Meningoencephalitis Patients Treated With Pulse Taper Corticosteroids for Post-infectious Inflammatory Syndrome (2021). *Clinical Infectious Diseases*, 73(9), e2789-e2798.

Wang, K., Dropulic, L., Bozekowski, J., Pietz, H. L., Jegaskanda, S., Dowdell, K., ... Cohen, J. I. (2021). Serum and Cervicovaginal Fluid Antibody Profiling in Herpes Simplex Virus (HSV) Seronegative Recipients of the HSV529 Vaccine. *The Journal of Infectious Diseases*.

Klumpp-Thomas, C., Kalish, H., Drew, M., Hunsberger, S., Snead, K., Fay, M. P., ... and Denson, J. P. (2020). Standardization of enzyme-linked immunosorbent assays for serosurveys of the SARS-CoV-2 pandemic using clinical and at-home blood sampling. *Nature Communications* 12.1, 1-13.

Dodd, L.E., Follmann, D., Wang, J., Koenig, F., Korn, L.L., Schoergenhofer, C., Proschan, M., Hunsberger, S., Bonnett, T., Makowski, M. and Belhadi, D., (2020). Endpoints for randomized controlled clinical trials for COVID-19 treatments. *Clinical Trials*, 17(5), pp.472-482.

Manning, J. E., Oliveira, F., Coutinho-Abreu, I. V., Herbert, S., Meneses, C., Kamhawi, S., ... and Cervantes-Medina, A. (2020). Safety and immunogenicity of a mosquito saliva peptide-based vaccine: a randomised, placebo-controlled, double-blind, phase 1 trial. *The Lancet*.

Pleguezuelos, O., James, E., Fernandez, A., Lopes, V., Rosas, L.A., Cervantes-Medina, A., Cleath, J., Edwards, K., Neitzey, D., Gu, W. and Hunsberger, S.,... (2020). Efficacy of FLU-v, a broad-spectrum influenza vaccine, in a randomized phase IIb human influenza challenge study. *NPJ vaccines*. 5(1), pp.1-9.

Zuñiga, J., Choreño-Parra, J. A., Jiménez-Alvarez, L., Cruz-Lagunas, A., Márquez, J. E., Ramírez-Martínez, G., ... and Cabello, C. (2020). A unique immune signature of serum cytokine and chemokine dynamics in patients with Zika virus infection from a tropical region in Southern Mexico. *International Journal of Infectious Diseases*.

Ravell, J. C., Matsuda-Lennikov, M., Chauvin, S. D., Zou, J., Biancalana, M., Deeb, S. J., ... and Morawski, A. (2020). Defective glycosylation and multisystem abnormalities characterize the primary immunodeficiency XMEN disease. *The Journal of clinical investigation*, 130(1), 507-522.

Hong, G. H., Ortega-Villa, A. M., Hunsberger, S., Chetchotisakd, P., Anunnatsiri, S., Mootsikapun, P., ... and Holland, S. M. (2020). Natural history and evolution of anti-interferon-autoantibody-associated immunodeficiency syndrome in Thailand and the United States. *Clinical Infectious Diseases*, 71(1), 53-62.

Gouel-Cheron, A., Lombard, K., Hunsberger, S., et. al. (2019). "Serial real-time RT-PCR and serology measurements substantially improve Zika and Dengue virus infection classification in a co-circulation area." *Antiviral research*, 172, 104638.

Kang, M., Grund, B., Hunsberger, S., Glidden, D., and Volberding, P. (2019). "Interim monitoring in a treatment strategy trial with a composite primary endpoint." *Contemporary clinical trials*, 86, 105846.

Noyola, D. E., Hunsberger, S., et.al (2019). "Comparison of rates of hospitalization between single and dual virus detection in a Mexican cohort of children and adults with influenza-like illness." *Open forum infectious diseases* (Vol. 6, No. 11, p. 424). US: Oxford University Press.

Peterson, R. L... INSIGHT FLU-IVIG study group. (2019). "Comparison of an ordinal endpoint to time-to-event, longitudinal, and binary endpoints for use in evaluating treatments for severe influenza requiring hospitalization." *Contemporary Clinical Trials Communications*, 100401.

Ferré, E. M., et. al. (2019). "Lymphocyte-driven regional immunopathology in pneumonitis caused by impaired central immune tolerance." *Science translational medicine*, 11(495), page 5597.

Dropulic, L. K. et.al. (2019). "A Randomized, Double-Blind, Placebo-Controlled, Phase 1 Study of a Replication-Defective Herpes Simplex Virus 2 Vaccine, HSV529, in Adults With or Without HSV Infection." *The Journal of infectious diseases*.

Gamiño-Arroyo, A. E. et. al. (2019). "Efficacy and safety of nitazoxanide in addition to standard of care for the treatment of severe acute respiratory illness." *Clinical Infectious Diseases*, 69(11), pages 1903-1911.

Moser, J. A. et. al. (2019). "Underweight, overweight, and obesity as independent risk factors for hospitalization in adults and children from influenza and other respiratory viruses". *Influenza and other respiratory viruses*, 13(1), pages 3-9.

Ortiz-Hernández, A. et. al. (2019). "Differential risk of hospitalization among single virus infections causing influenza-like illnesses". *Influenza and Other Respiratory viruses*, pages 36-43.

Hunsberger, Sally, and Matthew J. Memoli (2018). "Efficacy analysis in healthy-volunteer influenza challenge trials: intention to treat." *Antimicrobial agents and chemotherapy*

Marciano, Beatriz E., et al. (2018). "X-linked carriers of chronic granulomatous disease: Illness, lyonization, and stability." *Journal of Allergy and Clinical Immunology* pages 365-371.

Dropulic, L. et. al. (2017). "A replication-defective herpes simplex virus (HSV)-2 vaccine, HSV529, is safe and well-tolerated in adults with or without HSV infection and induces significant HSV-2-Specific antibody responses in HSV seronegative individuals." *Open forum infectious diseases* (Vol. 4, No. suppl 1, pp. S415-S416). US: Oxford University Press.

Peterson, R. L., Vock, D. M., Powers, J. H., Emery, S., Cruz, E. F., Hunsberger, S., ... INSIGHT FLU-IVIG Study Group. (2017). "Analysis of an ordinal endpoint for use in evaluating treatments for severe influenza requiring hospitalization". *Clinical Trials*, 14(3), pages 264-276.

Hunsberger, S. and Proschan, M. A. (2017). "Simple approaches to analyzing self-controlled case series (SCCS) data." *Statistics in Biopharmaceutical Research*, 9(1), pages 65-72.

Godfrey, C., Tauscher G, Hunsberger, S, Austin, M, Scott, L, Schouten, J, Leutkemeyer, A, Benson, C, Coombs, R, and Swindells, S (2016). "A survey of tuberculosis infection control practices at the NIH/NIAID/DAIDS-supported clinical trial sites in low and middle income countries" *BMC Infectious Diseases* 1.

Colombo R, Fiorentino, Dodd, L, Hunsberger S, Haney, C, Barrett, K, Nabha, L, Davey, R and Olivier K (2016). "A phase 1 randomized, double-blind, placebo-controlled, crossover trial of DAS181 (Fludase®) in adult subjects with well-controlled asthma." *BMC Infectious Diseases* 16.1 (2016): 1.

Ferre, Elise MN, et al. (2016). "Redefined clinical features and diagnostic criteria in autoimmune polyendocrinopathy-candidiasis-ectodermal dystrophy." *JCI Insight* 1.13.

Paulin-Prado, P, Nishimura, K, Freimanis-Harce L, Hunsberger S, et al (2016). "Clinical characteristics of asthmatic patients with influenza-like illness and risk of severe exacerbations in Mexico." *Annals of Allergy, Asthma & Immunology* 116.5 (2016): 402-407.

LoRusso PM et al. (2015). "Pilot trial of selecting molecularly guided therapy for patients iwth non-V600 BRAF mutant metastatic melanoma experience of the SU2C/MRA melanoma dream team." *Molecular Cancer Therapeutics* 1962–1971.

McShane, L and Hunsberger S (2015) "An Overview of phase II clinical trial designs with biomarkers" book chapter in *Design and Analysis of Clinical Trials for Predictive Medicine* 71–87. Shigeyuki Matsui, Marc Buyse and Richard Simon. (Editors) Chapman and Hall/CRC.

Hunsberger, S, Albert, PS and Thoma, M (2014). "Approaches to retrospective sampling for longitudinal transition regression model." *Statistics and its interface* 7.1 (2014): 75.

Schwandt A, Harris PJ, Hunsberger S, Deleporte A, Smith GL, Vulih D, Anderson BD and Ivy SP (2014). "The role of age on dose-limiting toxicities in phase I dose-escalation trials." *Clinical Cancer Research* 4768–4775.

Griffith, D, Adjemian, J, Brown-Elliott, Philley J, Prevots, R, Hunsberger S, Gaston C, Olivier K and Wallace R (2014) "The value of semi-quantitative mycobacterial cultures for predicting culture conversion during MAC lung disease therapy" *European Respiratory Journal* 246.

DeMichele, A, Berry, D., Zujewski, J, Hunsberger S, et. al. (2013). "Developing Safety Criteria for Introducing New Agents into Neoadjuvant Trials." *Clinical Cancer Research* 2817–2823.

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Takebe, N, Hunsberger, S and Yang, SX (2012). "Expression of GLi1 in the hedgehog signaling pathway and breast cancer recurrence." *Chinese Journal of Cancer Research* 24(4): 257–258.

Gupta, Sachin, Hunsberger, S. Boerner, Scott; et al (2012). "Meta-Analysis of the relationship between dose and benefit in phase I targeted agent trials." *Jounral of the National Cancer Institute* 104(24):1860–1866.

Fay, MP and Hunsberger S (2012). "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*, Chen, DG, Sun, J and Peace KE (editors) Chapman and Hall/CRC.

Wang, M, Dignam, J, Zhang, QE, DeGroot, JF, Mehta, MP, Hunsberger S (2012). "Integrated Phase II/III clincial trials in oncology; A case study." *Clinical Trials* 9(6):741–747.

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- Hunsberger, S, Albert, PS and Dodd, L (2010). "Analysis of progression-free survival data using a discrete time survival model that incorporates measurements with and without diagnostic error." *Clinical Trials* 7(6): 634–642.
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