

Sally Hunsberger-Candidate for RECOM



Employment:

Current Position:

Acting Director Office of Biostatistics Research, National Institute of Allergy and Infectious Diseases (NIAID)/National Institutes of Health (NIH) (January 1, 2026).

Prior Positions:

Deputy Director Office of Biostatistics Research, National Institute of Allergy and Infectious Diseases (NIAID)/National Institutes of Health (NIH) (May 2024 – January 1, 2026).

Mathematical Statistician, Biostatistics Research Branch, NIAID/NIH. (September 2013 – May 2024)

Mathematical Statistician, Biometrics Research Branch, National Cancer Institute. (1999-2013)

Mathematical Statistician, Office of Biostatistics, National Heart, Lung and Blood Institute (1991-1999).

Education:

Ph.D., Biostatistics, Medical College of Virginia, VCU, Richmond, Virginia, December 1990.

B.A., Mathematics and Biology, Goshen College, Goshen, Indiana, May 1986

Professional Innovation and Accomplishments (etc. research, teaching, management, leadership, and team-building):

Research Interests:

My research interests center on the design, conduct, oversight, and statistical analysis of clinical trials, with an emphasis on advancing methodology for studies conducted under complex or resource-constrained settings. My work spans clinical trial design, adaptive and innovative statistical methods, and the application of quantitative approaches to infectious disease and vaccine research.

A major area of interest is the role and operation of Data and Safety Monitoring Boards (DSMBs). As Executive Secretary of multiple DSMBs, I have contributed to the oversight of clinical trials across a broad range of therapeutic areas and have authored publications on DSMB practices, governance, interim monitoring, and the statistical issues that arise during trial oversight.

My methodological research focuses on clinical trial study design, particularly designs for human challenge studies and trials involving small or difficult-to-recruit populations, where efficient and rigorous statistical approaches are essential. I am interested in developing study designs that maximize scientific validity while maintaining participant safety and ethical standards.

My collaborative research has also focused on the analysis of immune responses to vaccines and infectious diseases. This includes statistical analyses of immunologic responses to COVID-19 vaccines, with an emphasis on identifying correlates of protection and characterizing variability in vaccine-induced immunity. In addition, I have conducted

research on antibody profile analysis following acute measles infection, using statistical methods to better understand immune responses and the dynamics of antibody development.

Publications (17 most relevant):

1. Hunsberger S, Ellenberg SS, Joffe S, Babiker A, Fix A, Griffin MR, Kalil J, Levine MM, Makgoba MW, Moore R, Tsiatis A, Whitley R. **Monitoring Multiple U.S. Government-Supported COVID-19 Vaccine Trials.** *NEJM Evidence.* 2023;2(3).
2. Li Y, Fay MP, Hunsberger S, Graubard BI. **Variable Inclusion Strategies for Effective Quota Sampling and Propensity Modeling: An Application to SARS-CoV-2 Infection Prevalence Estimation.** *Journal of Survey Statistics and Methodology.* 2023;11(5):1204–1228.
3. Hunsberger S, Long L, Reese SE, Shih JH. **Rank Correlation Inferences for Clustered Data With Small Sample Size.** *Statistica Neerlandica.* 2022.
4. Fay MP, Hunsberger S, Follmann D. **Risk Heterogeneity and the Illusion of Waning Vaccine Efficacy.** *Annals of Internal Medicine.* 2021.
5. Fay MP, Hunsberger S. **Practical Valid Inferences for the Two-Sample Binomial Problem.** *Statistical Surveys.* 2021;15:72–110.
6. Joffe S, Babiker A, Ellenberg SS, Fix A, Griffin MR, Hunsberger S, Kalil J, Levine MM, Makgoba MW, Moore R, Tsiatis A, Whitley R. **Data and Safety Monitoring of COVID-19 Vaccine Clinical Trials.** *Journal of Infectious Diseases.* 2021;224:1995–2000.
7. Kalish H, Klumpp-Thomas C, Hunsberger S, Baus HA, Fay MP, Siripong N, et al. **Undiagnosed SARS-CoV-2 Seropositivity During the First Six Months of the COVID-19 Pandemic in the United States.** *Science Translational Medicine.* 2021;13(601).
8. Hunsberger S, Ortega-Villa AM, Powers JH III, León HAR, Sosa SC, Hernández ER, et al. **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.* 2020;98:241–248.
9. Hunsberger S, Proschan MA. **Simple Approaches to Analyzing Self-Controlled Case Series (SCCS) Data.** *Statistics in Biopharmaceutical Research.* 2017;9(1):65–72.
10. Hunsberger S, Albert PS, Thoma ME. **Approaches to Retrospective Sampling for Longitudinal Transition Regression Models.** *Statistics in Interface.* 2014;7:75–85.
11. Hunsberger S, Albert PS, Dodd L. **Analysis of Progression-Free Survival Data Using a Discrete Time Survival Model That Incorporates Measurements With and Without Diagnostic Error.** *Clinical Trials.* 2010;7(6):634–642.
12. Hunsberger S, Zhao Y, Simon R. **A Comparison of Phase II Study Strategies.** *Clinical Cancer Research.* 2010;15(19):5950–5955.
13. Hunsberger S, Graubard BI, Korn EL. **Testing Logistic Regression Coefficients with Clustered Data and Few Positive Outcomes.** *Statistics in Medicine.* 2008;27(8):1305–1324.
14. Hunsberger S, Rubinstein LV, Dancey J, Korn EL. **Dose Escalation Trial Designs Based on a Molecularly Targeted Endpoint.** *Statistics in Medicine.* 2005;24:2171–2181.
15. Albert PS, Hunsberger SA, Hu N. **Identifying Multiple Changepoints in Heterogeneous Binary Data with an Application to Molecular Genetics.** *Biostatistics.* 2004;5(4):515–526.
16. Hunsberger S, Albert PS, Follmann DA, Suh E. **Parametric and Semiparametric Approaches to Testing for Seasonal Trend in Serial Count Data.** *Biostatistics.* 2002;3(2):289–298.
17. Proschan MA, Hunsberger S. **Designed Extension of Studies Based on Conditional Power.** *Biometrics.* 1995;51:1315–1324.

Honors Include:

2025: Fellow of the American Statistical Association.

2022: NIH Director's Group Award for the contributions to the NIAID sponsored Covid-19 research efforts.

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.

Service to the Profession (etc. ENAR and other professional societies):

Editorial Activities:

Associate Editor, Statistics in Biopharmaceutical Research, Jan 2026- present.

Editorial board Journal of Clinical Oncology 2019-2022.

Service and Committee Work for the Profession:

Education advisory committee for Eastern North American Region statistical (ENAR) meetings, 2024

Program committee member for ENAR meetings, 2021

Member American Statistical Association and Biometric Society Human Rights Committee, 2009-2012

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

Member and Ad-hoc member of different FDA Advisory Committee's; CBER's Cellular Tissue and Gene Therapies, Gastrointestinal Drug, Oncologic Drugs, and Bone, Reproductive and Urologic Drugs.

Additional Leadership Roles:

I was the Executive Secretary for the Operation Warp speed COVID-19 Vaccine Data and Safety Monitoring Board (DSMBs), I provided scientific and operational leadership for the independent oversight of the pivotal Phase III clinical trials evaluating COVID-19 vaccines. In this role, I played a central role in establishing the Board by identifying and recruiting members with the appropriate scientific, clinical, statistical, and ethical expertise and ensuring balanced representation

and independence. I coordinated the review of interim safety and efficacy data, supported DSMB deliberations and recommendations, and ensured that trial monitoring adhered to the highest standards of scientific rigor, participant safety, and regulatory compliance. This work contributed to the timely and objective evaluation of vaccine safety and efficacy during the COVID-19 pandemic and helped maintain the integrity and credibility of the U.S. Government's vaccine clinical trial program.

I have served as a Biostatistical faculty member for the annual CReDO Oncology Clinical Research Workshop in India since its inception. In this role, I have provided training in clinical trial design and statistical methodology to early career oncologists and statisticians. Beyond being a faculty member, I have contributed to the strategic development of the workshop, helping to shape its vision and expand its impact by strengthening statistical expertise and building clinical trial research capacity within the Indian oncology community.