DEAN FOLLMANN

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April 9, 2014

EDUCATION

1981-85 Carnegie Mellon University. Ph.D. in Statistics. Dissertation advisor, [redacted] (b) (6). Dissertation topic: *Nonparametric Mixtures of Logistic Regression Models.*

1980-81 Northern Illinois University. M.S. in Statistics.

1978-80 Northern Illinois University. B.S. in Mathematics and Psychology, *cum laude.*

1975-77 Elgin Community College. A.A. in Psychology.

HONORS

NIH Directors Award 2010.

Best Paper in *Biometrics* 2009: Chop-Lump Tests for Vaccine Trials. Also selected in 2013 as one of 15 classic Biometrics papers.

NIH Merit Award 1993, 2008.

NIAID Merit Award 2011.

Fellow of the American Statistical Association 2003.

Carnegie Mellon University's "Statistics Student of the Year", 1984.

Member Sigma Xi, Phi Kappa Phi, Pi Mu Epsilon, and Phi Theta Kappa.

National Research Service Award Fellowship, 1981-85.

JOBS

2002-present National Institute of Allergy and Infectious Diseases. Assistant Director for Biostatistics, NIAID and Chief of the Biostatistics Research Branch. Head a group of statisticians who are involved in overseeing large multi-center studies, collaborating in medical studies, and conducting independent statistical research. Also serve on the NIAID Executive Committee.

1988-2002 National Heart, Lung, and Blood Institute. Involved in the design and analysis of clinical trials and epidemiological studies. Experience with several large multi-center investigations involving cardiovascular disease, diabetes, emphysema, HIV infection, heart failure, hypertension, and transfusion therapies. Also conducted independent statistical research and collaborated in small studies of various disease and therapies.

1985-88 Center for Naval Analyses. Directed and collaborated in studies involving Navy manpower, surface ship readiness, and the reliability of electronic systems. Top Secret

security clearance.

1984 RAND Corporation. Developed models to predict occupational choices of Air Force enlisted personnel at reenlistment.

PROFESSIONAL EXPERIENCE

Committees, Panels, Boards

Member of the Food and Drug Administration (FDA) Antiviral Drugs Advisory Committee, 2013-present.

Panelist for Workshop on Ethical Considerations Around Novel Combination Prevention Modalities in HIV Prevention and Vaccine Trials in Resource Limited Settings, April 2013

Member of the Department of Statistics Advisory Board for Carnegie Mellon University, April 2013.

Member of the Scientific Steering Committee for Project Phidisa—a Clinical Trials Network in the South African National Defence Force 2011-present.

Member of the Biomarkers Consortium of the Foundation for NIH 2010-present.

Member of the Advisory Board of the George Mason University Department of Statistics 2009-2013.

Panelist for the Antibacterial Drug Development Council of the Brookings Institution 2012.

Panelist on the Statistical Think Tank for Antibacterial Drug Development, Clinical Trials Transformation Initiative August 2012.

ENAR Educational Advisory Committee 2012.

Chair of the Scientific Advisory Board for the Vaccine Immunology Statistical Center of the Collaboration for AIDS Vaccine Development Program of the Bill & Melinda Gates Foundation 2009-present.

Member of a Peer Review Panel for the Division of HIV/AIDS Prevention of the CDC April 2009.

Member of a Special Review Panel for the Biometry Research Group of the National Cancer Institute, Spring 2008.

Member of the Board of Scientific Counselors for the review of the Laboratory of Epidemiology, Demography, and Biometry of the National Institute on Aging, May 2008.

Member of the Food and Drug Administration (FDA) Anti-Infective Drugs Advisory Committee, 2008-2011.

Guest of the FDA Over-the-counter Advisory Committee Meeting, December 2007.

Guest of the FDA Joint Advisory Committee meeting on Ketek, December 2006.

Member WHO-UNAIDS Technical Consultation on Clinical Trial Design of Novel Concepts to Determine HIV Vaccine Efficacy, Feb 2006.

Member of the FDA Endocrinologic and Metabolic Drugs Advisory Committee 2002-2006.

Member of the Advisory Panel on Use of Generics in ACTG Protocols, 2006-present.

Guest of the FDA Anti-Infective Drugs Advisory Committee meeting on Factive, March 2006.

Panel discussant at the workshop for "Future Clinical Trials Issues in Multiple Sclerosis," Washington, DC. December 2004

Member of the External Advisory Committee to the HIV Vaccine Trials Network 2004.

Member of the NICHD/FDA Newborn Drug Development Initiative Cardiology Working Group, 2004.

Member of the Partnership in AIDS Vaccine Evaluation (PAVE) Efficacy Trial Design Working Group 2004-2008.

Guest to the FDA Biological Response Modifiers Advisory Committee July 1998.

Editorial Service

Associate Editor, *Statistics in Biopharmaceutical Research*, 2007-present.

Associate Editor, *Biometrics*, 2005-2011.

Associate Editor, *Journal of Biopharmaceutical Statistics*, 2000-present.

Editorial Board, *Statistical Communications in Infectious Diseases* 2009-2012.

Consulting Statistician, *Blood*, 1999-present.

Referee for *American Journal of Epidemiology, American Statistician, Annals of Statistics, Annals of Applied Statistics, Blood, Biometrics, Biometrika, Biostatistics, British Medical Journal, Clinical Infectious Diseases, Communications in Statistics, Computational Statistics and Data Analysis, Contemporary Clinical Trials, Epidemiologic Reviews, IEEE Transactions on Information Theory, Infectious Diseases in Obstetrics and Gynecology, International Journal of Statistics and Management Systems, Journal of the American Statistical Association, Journal of Circadian Rhythms, Journal of Business and Economic Statistics, Journal of Biopharmaceutical Statistics, Journal of Interferon & Cytokine Research, Journal of The Royal Statistical Society: Series B, Journal of Statistical Computation and Simulation, New England Journal of Medicine, Psychological Bulletin, Psychometrika, Resuscitation, Retrovirology, Statistics in Biopharmaceutical Research, Statistical Communications in Infectious Diseases*, and *Statistics in Medicine*.

Data & Safety Monitoring Boards

Member of the Coronary Clinical Trial DSMB, 2010-2013.

Member of the NHLBI INTERMACS–Interagency Registry of Mechanically Assisted Circulatory Support– DSMB, 2006-present.

Member of the NHLBI Cardiology Data Safety and Monitoring Board for Intramural Studies, 2000-present.

Chair of the NCI/Center for Cancer Research Data Safety and Monitoring Board, 2009-present.

Co-chair of the NCI/Center for Cancer Research Data Safety and Monitoring Board, 1999-2009.

Member Data Safety and Monitoring Board for the Esophageal Squamous Dysplasia Chemoregression Trial in Linxian, China, sponsored by NCI, 1999-2001.

Member of an NHLBI Data Safety and Monitoring Board for studies of pacemakers in patients with cardiomyopathy, 1997-2000.

Other

Reviewer for a Statistical Proposal to Research Foundation - Flanders (Fonds Wetenschappelijk Onderzoek - Vlaanderen, FWO) 2013.

PhD dissertation committee member for [redacted] (b) (6) 2011.

PhD dissertation committee member for [redacted] (b) (6) 2010.

Invited roundtable discussion leader on "Statistics at NIH", ENAR March 2008.

Organizer of a Blue Ribbon Panel to examine the role of Epidemiology at NIAID, 2005.

Reviewer for Gates Foundation 2004.

Co-organizer of the workshop "Endpoints and Regulatory Issues in HIV Vaccine Clinical Trials", 2004.

Chair of the VAX004 Analysis Committee 2003. Provided an independent analysis of the first Phase III trial of an HIV vaccine and briefed various groups on the results, 2003-2004.

Project Officer for a 5 year, $5M contract to design, implement, and maintain a clinical research database and provide for statistical analysis for the Division of Intramural Research, National Heart, Lung, and Blood Institute, 2001-2002.

ENAR van Ryzin student paper award committee Fall 1999.

Member of an expert panel on intramural promotion for the National Institute of Child Health and Development, 1999.

Member of the Regional Advisory Board of the Biometric Society-ENAR 1998-2000.

Consultant to the Cardiovascular Research Institute, George Washington University 1997. Provided advice concerning the design, monitoring and sample size of an equivalence study.

Member of an External Review Board for hiring for the FDA, 1995.

Section Chair for Public Health and Biostatistics, Washington Statistical Society 1992-93.

Member of the Review Committee for the Anti-epileptic Drug Development Program of the National Institute of Neurological Disorders and Stroke, 1992.

Consultant to Research Consultants Incorporated. Modified and programmed a random effects model for application to Navy retention data. 1988.

Member of the American Statistical Association, the Biometric Society, and the Washington Statistical Society.

Fellow of the Royal Statistical Society.

STATISTICAL PUBLICATIONS

[redacted] (b) (4)

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Qin J, & **Follmann DA** "Semiparametric maximum likelihood inference by using number of failed contact attempts to adjust for non-ignorable non-response" *under revision*

[redacted] (b) (4)

Li, S, Huang, CY, **Follmann, DA**, Jose JM, Brahmadathan, KN, & Krause RM "Recurrent event analysis using time-varying covariates with application to the impact of streptococcus on pharyngitis in Indian school children" *under revision*

Hu, Z, **Follmann DA** "Acute-to-chronic ratio as a metric for HIV surveillance" to appear *Open Journal of Statistics*

Follmann, DA, Qin J, Gessner B, Guerrero ML, Ruiz-Palacios, GM "Estimating the burden of pertussis in Mexico using repeated antibody levels," to appear, *Journal of the Royal Statistical Associateion: Series C.*

Hu, Z, Qin J, **Follmann DA** "Semiparametric mixture survival model with application to MRFIT study" to appear *Statistics and its Interface*

Follmann DA, Brittain E, Powers JH "Discordant MIC Analysis: A New Path to Licensure for Anti-infective Drugs," *Clinical Trials* 2013 10 876-885.

Brittain E, Fay, M, & **Follmann, DA** "A valid approach to noninferiority testing with historical random effects meta-analysis" *Biostatistics* 2012 13(4) 637-649.

Hu, Z, **Follmann, DA**, & Qin J "Semiparametric double balancing score estimation for incomplete data with ignorable missingness" *Journal of the American Statistical Association* 2012 107 247-257.

Follmann, DA "Comment on Probabilistic Index Models" *Journal of the Royal Statistical Society: Series B*, 2012 75 623-671.

Follmann, DA & Fay M. "Bounds on the effect of vaccine induced immune response on outcome" *International Journal of Biostatistics*, 2012 8(2).

Follmann, DA & Proschan M "A test of location for exchangeable multivariate normal data with unknown correlation" *Journal of Multivariate Analysis* 2012; 104 115-125.

Huang, CY, Qin, J, & **Follmann DA** "A maximum pseudo-profile likelihood estimator for the Cox model with length-biased sampling" *Biometrika* 2012 1-12.

Follmann DA "Comment on A Sequential Phase 2b Trial Design for Evaluating Vaccine Efficacy and Immune Correlates for Multiple HIV Vaccine Regimens," *Statistical Communications on Infectious Diseases*, 2011 3(1).

Brittain E & **Follmann, DA** "A hierarchical rank test for crossover trials with censored data" *Statistics in Medicine*, 2011; 3507-3519.

Follmann, DA & Nason M "An augmented probit model for missing predictable covariates

in quantal bioassay with small sample size" *Biometrics* 2011; 67 1127-1134.

Huang CY, Luo X, & **Follmann, DA** " "A model checking method for the proportional hazards model with recurrent gap time data," *Biostatistics* 2011; 12 535-547.

Hu, Z, **Follmann, DA**, & Qin J "Dimension reduced kernel estimation for distribution function with incomplete data" *Journal of Statistical Planning and Inference* 2011; 3084-3093.

Nason, M, **Follmann, DA** "Design and analysis of crossover trial designs for absorbing binary endpoints," *Biometrics* 2010; 958-965.

Hu, Z, **Follmann, DA**, & Qin J "Semiparametric dimension reduction estimation for mean response estimation with missing data" *Biometrika* 2010; 97 305-319.

Follmann, DA & Fay M, "Exact Inference for Complex Clustered Data Using Within Cluster Resampling," *Journal of Biopharmaceutical Statistics* 2010; 20(4) 850-869.

Follmann, DA, Qin J, Hoshino Y. "Estimation of viral infection and replication in cells using convolution models," *JRSS-C: Applied Statistics* 2010; 59 423-435.

Follmann DA, Fay M, & Proschan M "Chop-lump tests for vaccine trials," *Biometrics* 2009; 65 885-893. Selected as Best Paper in Biometrics 2009. Also selected as one of 15 classic Biometrics papers 2013.

Huang, CY, Qin, J, & **Follmann DA** "Empirical likelihood-based estimation of treatment effect in a pretest-posttest study," *Journal of the American Statistical Association* 2008; 103 1270-1280.

Hu, Z, Qin J, & **Follmann DA** "Semiparametric two-sample changepoint model with application to human immunodeficiency virus studies *JRSS-C: Applied Statistics* 2008; 57(5) 589-607

Hu, Z, **Follmann DA**, Qin, J. Dewar R, Sangweni, P "A Nonparametric Likelihood Test for Detecting Discordance between Two Measurements with Application to Censored Viral Load Determinations," *Statistics in Medicine* 2008; 27(22) 4489-4501.

Proschan M. A, & **Follmann, DA** "Cluster Without Fluster: The Effect of Correlated Outcomes on Inference in Randomized Clinical Trials," *Statistics in Medicine* 2008; 27 795-809.

Brittain, E, **Follmann, DA**, & Song Y. "Dynamic Comparison of Kaplan-Meier Proportions: Monitoring a Randomized Clinical Trial with a Long Term Binary Endpoint," *Biometrics* 2008; 64: 189-197.

Qin L, Gilbert, P, **Follmann DA** & Li D. "Assessing Surrogate Endpoints in Vaccine Trials with Case-Cohort Sampling and the Cox Model" *Annals of Applied Statistics* 2008; 1: 386-407.

Albert, P.S. & **Follmann, DA** "Random Effects and Latent Processes Approaches for Analyzing Binary Longitudinal Data with Missingness: A Comparison of Approaches Using Opiate Clinical Trial Data," *Statistical Methods for Medical Researchers* 2007; 16 417-439.

Fay, M.P., Halloran M.E., & **Follmann, DA** "Accounting for Variability in Sample Size Esti-

mation with Applications to Nonadherence and Estimate of Variance and Effect Size," *Biometrics* 2007; 63 465-474.

Hu, Z., & **Follmann, DA** "Statistical Methods for Active Extension Trials," *Statistics in Medicine* 2007; 26 2433-2448.

Follmann, DA "Augmented Designs to Assess Immune Response in Vaccine Trials," *Biometrics* 2006; 62 1161-1169.

Marron JS, Muller HG, Rice J, Wang JL, Wang NY, Wang YD, Davidian M, Diggle P, **Follmann DA**, Louis TA, Taylor J, Zeger S, Goetghebeur E, Carroll RJ "Discussion of nonparametric and semiparametric regression" *Statistica Sinica* 2004; 14 615-629.

Proschan M. A & **Follmann, DA**, "A Permutation Approach to the Behrens-Fisher Problem," *Journal of the Korean Statistical Society* 2004; 33 79-97.

Stylianou, M. & **Follmann, DA** "The Accelerated Biased Coin Up-and-Down Design in Phase I Trials," *Journal of Biopharmaceutical Statistics* 2004; 14 249-260.

Wu, C.O., Zheng, G., Leifer, E., **Follmann, DA**, & Lin, J.P. "A Statistical Method for Adjusting Covariates in Linkage Analysis with Sib Pairs," *Biomed Central Genetics* 2003; 31; 4 Suppl 1:S51.

"Comparing HLA Antigen Frequencies Between Two Groups," **Follmann, DA** *Statistics in Medicine* 2003; 22 1999-2013.

Follmann, DA, Proschan M.A. & Leifer, E. "Multiple Outputation: Inference for Complex Multivariate Data by Averaging Analyses From Univariate Data," *Biometrics* 2003; 59 420-429.

Albert, P.S. & **Follmann, DA** "A Random Effects Transition Model for Longitudinal Binary Data with Informative Missingness," *Statistica Neerlandica* 2003; 57 100-111.

Follmann, DA, "Regression Analysis Based on Pairwise Ordering of Patients' Clinical Histories," *Statistics in Medicine* 2002; 21 3353-3367.

Albert, P.S. & **Follmann, DA**, Wang, S.A., & Suh, E. "A Latent Process Model for Longitudinal Binary Data Subject to Nonignorable Missingness," *Biometrics* 2002; 58 631-642.

Hunsberger, S., Albert, P. S., & **Follmann, DA**, & Suh, E. "Parametric and Semiparametric Approaches to Testing for Seasonal Trend in Serial Count Data," *Biostatistics* 2002; 289-298.

Fay, M. P. & **Follmann, DA**,"Designing Monte Carlo Implementations of Permutation or Bootstrap Hypothesis Tests," *American Statistician* 2002; 56 63-70.

Hunsberger, S. & **Follmann, DA** "Testing for Treatment and Interaction Effects in Semiparametric Analysis of Covariance," *Statistics in Medicine*, 2001; 20 1-19.

Follmann, DA "On the Effect of Treatment Among Treatment Compliers: An Analysis of the Multiple Risk Factor Intervention Trial," *Journal of the American Statistical Association*, 2000; 95 1101-1109.

Albert, P.S. & **Follmann, DA** "Modeling Repeated Count Data Subject to Informative Dropout," *Biometrics*. 2000; 56 667-677.

Follmann, DA & Proschan, M.A., "A Multivariate Test of Interaction for Use in Clinical Trials," *Biometrics*. 1999; 55 1151-1155.

Follmann, DA & Proschan, M.A., "Valid Inference in Random Effects Meta-analysis," *Biometrics*. 1999; 55 732-737.

Follmann, DA & Proschan, M.A., "A Simple Permutation-Type Method for Testing Circular Uniformity with Correlated Angular Measurements," *Biometrics*, 1999; 55 782-791.

Follmann, DA & Albert,P.S., "Bayesian Monitoring of Event Rates with Censored Data," *Biometrics*, 1999; 55 603-607.

Follmann, DA, Hunsberger, S, & Albert, P.S. "Repeated Probit Regression When Covariates Are Measured With Error," *Biometrics*, 1999; 55 403-409.

Wu M., & **Follmann, DA** "Use of Summary Measures to Adjust for Informative Missingness in Repeated Measures with Random Effects," *Biometrics*, 1999; 55 75-84.

Geller, N. L., Proschan, M. A., & **Follmann, DA** "Group Sequential Monitoring of Multi-Armed Clinical Trials,' *Drug Information Journal*, 1999; 33 479-486.

Gu, M., **Follmann, DA**, & Geller, N. "Monitoring a General Class of Two Sample Survival Statistics with Applications," *Biometrika*, 1999; 86 45-58.

Follmann, DA "Adaptively Changing Subgroup Proportions in Clinical Trials," *Statistica Sinica*, 1997; 7 1085-1102.

Albert, P.S. & **Follmann, DA**, Barnhart, H. X. "A Generalized Estimating Equations Approach for Modeling Multivariate Random Length Binary Data," *Biometrics*, 1997; 53 1116-1124.

Proschan, M. & **Follmann, DA** "A Restricted Test of Circadian Rhythm," *Journal of the American Statistical Association* 1997; 92 717-724.

Follmann, DA "Long Term Followup in AIDS Clinical Trials: Discussion," *Statistics in Medicine*, 1996; 15 2367-2370.

Follmann, DA "A Simple Multivariate Test for One Sided Alternatives," *Journal of the American Statistical Association*, 1996; 91 854-861.

Proschan, M. A. & **Follmann, DA** "One Experiment or Many? The Effect of a Single Control on the Distribution of Type I Errors," *American Statistician*, 1995; 49 144-149.

Follmann, DA "Multivariate Tests for Multiple Endpoints in Clinical Trials," *Statistics in Medicine*, 1995; 14 1163-1176.

Geller, N., Proschan, M., & **Follmann, DA** "Group Sequential Monitoring of Multi-Armed Clinical Trials," *Drug Information Journal*, 1995; 29 705-713.

Follmann, DA & Wu, M. "An Approximate Generalized Linear Model With Random Effects For Informative Missing Data," *Biometrics*, 1995; 51 151-168.

Proschan, M. A., **Follmann, DA** & Geller, N.L. "Monitoring Multi-Armed Trials," *Statistics in Medicine*, 1994; 13 1441-1452.

Follmann, DA, Proschan, M. A. & Geller, N. L. "Monitoring Multi-Armed Trials," *Bio-*

metrics 1994; 50 325-336.

Follmann, DA & Proschan, M. A. "The Effect of Estimation and Biasing Strategies On Selection Bias in Clinical Trials with Permuted Blocks," *Journal of Statistical Planning and Inference*, 1994; 39 1-17.

Follmann, DA "Modeling Transitional and Joint Marginal Distributions in Repeated Categorical Data," *Statistics in Medicine*, 1994; 13 467-477.

Follmann, DA, Wu, M., & Geller, N. "Testing Treatment Efficacy in Clinical Trials With Repeated Binary Measurements and Missing Observations," *Communications in Statistics: Theory and Methods*, 1994; 23(2) 557-574.

Proschan M. A., **Follmann, DA** & Waclawiw, M. "Effects of Assumption Violations on Type I Error Rate in Sequential Monitoring" *Biometrics* 1992; 48(4) 1131-1144.

Follmann, DA "Growth Curve Models Under Order Restrictions," *Communication in Statistics: Theory and Methods*, 1992; 21(10) 2775-2807.

Follmann, DA, Elliott, P., Cutler, J., & Suh, I. "Variance Imputation for Overviews of Clinical Trials with Continuous Response," *Journal of Clinical Epidemiology*, 1992; 45(7) 769-773.

Follmann, DA, Wittes, J. & Cutler, J. "A Clinical Trial Endpoint Based on Subjective Rankings," (with discussion) *Statistics in Medicine*, 1992; 11(4) 427-438.

Follmann, DA, Wittes, J. & Cutler, J. "Rejoinder", *Statistics in Medicine* 1992; 11(4) 453-454.

Follmann, DA "The Effect of Screening on Some Pretest-Posttest Test Variances," *Biometrics* 1991; 47 763-771.

Follmann, DA & Lambert, D. "Identifiability of Finite Mixtures of Logistic Regression Models," *Journal of Statistical Planning and Inference*; 1991; 27 375-381.

Follmann, DA "Modeling Failures of Intermittently Used Machines," *Applied Statistics* 1990; 39(1) 115-123.

Follmann, DA & Lambert, D. "Generalizing Logistic Regression by Nonparametric Mixing," *Journal of the American Statistical Association* 1989; 84 295-300.

Follmann, DA & Goldberg, M. "Distinguishing Heterogeneity from Decreasing Hazard Rates," *Technometrics* 1988; 30(4) 389-396.

Follmann, DA "Consistent Estimation in the Rasch Model Based on Nonparametric Margins," *Psychometrika* 1988; 53(4) 553-562.

MEDICAL PUBLICATIONS

Melbin-Jose JJ, Brahmadathan KN, Abraham VJ, **Follmann DA**, Huang CY, Liu X, Hoe NP, Krause RM6 "Streptococcal pharyngitis in school children in south India," to appear *Indian Journal of Medical Research*

Talaat KR, Luke CJ, Khurana, S, Manischewitz J, King LR, McMahon BA, Karron RA, Lewis K, Qin J, **Follmann DA**, Golding H, Neuzil K, Subbarao K "A live attenuated H5N1

vaccine induces long-term immunity in the absence of a primary antibody response," to appear *Journal of Infectious Diseases.*

Hurley A, Smith M, Karpova T, Hasley RB, Belkina N, Shaw S, Balenga N, Druey KM, Nickel E, Packard B, Imamichi H, Hu Z, **Follmann D**, McNally J, Higgins J, Sneller M, Lane HC, Catalfamo M "Enhanced effector function of CD8 T cells from healthy controls and HIV infected patients occurs through thrombin activation of the Protease-activated receptor-1" *Journal of Infectious Diseases* 2013; 207(4) 638-650.

Fay, MP, **Follmann DA**, Lynn F, Quinn C, Schifer J, Kohberger B, Stark G, & Nuzum E. " Anthrax Vaccine Induced Antibodies Provide Cross Species Prediction of Survival to Aerosol Challenge," *Science Translational Medicine* 2012; 4 (151).

Lee M, Lee J, Carroll MW, Choi H, Min S, Song T, Via L, Goldfeder L, Kang F, Jin B, Park H, Kwak H, Kim H, Jeon S, Jeong I, Joh J, Chen R, Olivier K, Shaw P, **Follmann DA**, Song S, Lee JK, Lee D, Kim C, Dartois V, Park S, CHo S, Barry C, "Linezolid for the Treatment of Chronic Extensively Drug-Resistant Tuberculosis" *New England Journal of Medicine* 2012; 367 (16) 1508-1518.

Ledwaba L, Tavel JA, Khabo P, Maja P, Qin J, Sangweni P, Liu X, **Follmann DA**, Metcalf JA, Orsega S, Baseler B, Neaton JD, Lane HC "Pre-ART plasma levels of inflammation and coagulation markers are strong predictors of death in a South African cohort with advanced HIV disease," *PLOS One* 2012; 7 (3) e24243

De Pascalis R, Chou AY, Bosio CM, Huang CY, **Follmann DA** & Elkins KS "Development of functional and molecular correlates of vaccine-induced protection for a model intracellular pathogen, *F. tularensis* LVS" *PLOS-Pathogens* 2012; 8 (1) e1002494.

Dlamini, J, Hu Z, Ledwaba J, Morris L, Maldarelli F, Dewar R, Highbarger H, Somaroo H, Sangweni P, **Follmann DA**, Pau A, "Genotypic Drug Resistance at Viral Rebound among Patients who received Lopinavi/ritonavir or Efavirenz-based first line antiretroviral therapy in South Africa," *Journal of Acquired Immune Deficiency Syndromes* 2011; 304-308.

Dlamini JN, Hu Z, Somaroo H, Highbarger H, **Follmann DA**, Dewar R, Pau A "Lack of Effect from a Previous Single Dose of Nevirapine on Virologic and Immunologic Responses After 6 Months of Antiretroviral Regimens Containing Either Efavirenz or Lopinavir-Ritonavir," Regimen in a Cohort of South African HIV+ Women," *Pharmacotherapy* 2011; 158-163.

Ganesan A, Crum-Cianflone N, Higgins J, Qin J, Rehm C, Metcalf J, Brandt C, Vita J, Decker C, Sklar P, Bavaro M,Tasker S, **Follmann DA**, Maldarelli F. " High Dose Atorvastatin Decreases Cellular Markers of Immune Activation without Affecting HIV-1-RNA Levels: Results of a Double-Blind Randomized Placebo Controlled Clinical Trial" *Journal of Infectious Diseases* 2011; 756-764.

Ho J, Moir S, Wang W, Posada JG, Gu WJ, Rehman MT, Dewar R, Kovacs C, Sneller MC, Chun TW, **Follmann DA**, Fauci AS "Enhancing effects of adjuvanted 2009 pandemic H1N1 influenza A vaccine on memory B-cell responses in HIV-infected individuals" *AIDS* 2011; 295-302.

Tavel JA, Huang CY, Shen J, Metcalf JA, Dewar R, Shah A, **Follmann DA**, Herpin B, Davey RT, Polis MA, Kovacs J, Masur H, Lane C "Interferon Alpha Produces Significant

Decreases in HIV Load" *Journal of Interferon & Cytokine Research* 2010; 30 461-464.

Willey R, Nason M, Nishimura Y, **Follmann DA**, & Martin MA "Neutralizing Antibody Titers Conferring Protection to Macaques From a Simian/Human Immunodeficiency Virus Challenge Using the TZM-bl Assay," *AIDS Research and Human Retroviruses* 2010; 26 89-98.

Lim JK, McDermott DH, Lisco, A, Foster GA, Krysztof D, **Follmann DA**, Stamer, SL, & Murphy, PM. "CCR5 Deficiency is a Risk Factor for Early Clinical Manifestations of West Nile Virus Infection, but not for Infection per se," *Journal of Infectious Diseases* 2010; 201 178-185.

Ganesan A, Chattopadhyay PK, Brodie TM, Qin J, Gu W, Mascola JR, Michael NL, **Follmann DA**, & Roederer M and the IDCRP HIV Working Group "Immunological and Virological Events in Early HIV Infection Predict Subsequent Rate of Progression," *Journal of Infectious Diseases* 2010; 2 272-284.

Hoshino Y, Katano H, Zou P,Hohman P, Marques A,Tyring SK, **Follmann DA**, Cohen JI "Long Term Administration of Valacyclovir Reduces the Number of Epstein-Barr Virus (EBV)-Infected B cells, but not the Number of EBV DNA Copies per B Cell in Healthy Volunteers," *Journal of Virology* 2009; 83 11857-11861.

Weintrob AC, Wu W, Qin J, Robertson J, Ganesan A, Crum-Ciaflone NF Landrum ML, Wortmann G, Robertson J, **Follmann DA**, Agan BK. "Syphilis Co-Infection Does Not Affect HIV Disease Progression," *International Journal of STD and AIDS* 2010; 21 57-59.

Lim JK, Lisco A, McDermott DH, Huynh L, Ward JM, Faucette LJ, Johnson B, Johnson H, Pape J, **Follmann DA**, Margolis LB, & Murphy, PM. "Genetic Variation in OAS1 is a Risk Factor for Initial Infection with West Nile in Man," *PLos Pathogens* 2009; 5 (2).

Migueles SA,Osborne CM,Royce C,Compton AA,Joshi RP,Weeks KA,Rood JE,Berkley AM,Sacha JB, Cogliano-Shutta NA, Lloyd M,Roby G, Kwan R, McLaughlin M, Stallings S, Rehm C,O'Shea MA, Mican J,Packard BZ, Komoriya A,Palmer S, Wiegand AP, Maldarelli F,Coffin JM, Mellors JW,Hallahan CW,**Follmann DA**, Connors M "Lytic Granule Loading of CD8(+) T Cells Is Required for HIV-Infected Cell Elimination Associated with Immune Control," *Immunity*, 2008; 29 1009-1021.

Healey LM, Hahn BK, Rehm CA, Adelsberger J, Qin J, **Follmann DA**, Tavel J, Kovacs JA, Sereti I,Davey R, "The Effect of Continuous Versus Pericycle Antiretroviral Therapy on IL-2 Responsiveness," *Journal of Interferon & Cytokine Research* 28 455-462.

Catalfamoa M,Di Mascio M, Hu Z, Srinivasula S, Thakera V, Adelsbergerd J, Rupert A, Baseler M, Tagaya Y, Roby G, Rehm C, **Follmann DA**, & Lane, HC "HIV infection-associated immune activation occurs by two distinct pathways that differentially affect CD4 and CD8 T cells," *Proceedings of the National Academy of Sciences* 2008; 105 19851-19856.

Fogli M, Mavilio D, Brunetta E, Varchetta S, Ata K, Roby G, Kovacs C, **Follmann DA**, Pende D, Ward J, Barker E, Marcenaro E, Moretta A, & Fauci AS, Lysis of endogenously infected CD4+ T cell blasts by rIL-2 activated autologous natural killer cells from HIV-infected viremic individuals *PLoS Pathogens* 2008; 4 1000101; 1-12.

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Follmann, DA Review of "Statistics in Clinical Practice,"Second Edition, BMJ Books, by David Coggon. *Journal of Epidemiology and Community Health* 2004; 58, 963.

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Follmann, DA "Primary Efficacy Endpoint," Encyclopedia of Clinical Trials, *John Wiley & Sons* 2007.

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INVITED PRESENTATIONS

"So Many Trials, So Little Time: Promise and Pitfalls of Meta-analysis" Conference on Retroviruses and Opportunistic Infections, March 2014.

"An Overview of Vaccine Efficacy" Webinar for the Vaccines Subcommittee of the International Society for Clinical Biostatistics, December 2013.

"Vaccine Efficacy: The Virion's View" Vanderbilt Univeristy, October 2013.

"Strengths and Weakness of Clinical Trials and Observational Studies" Second David Sackett Symposium:"Is It Time to Retire The Randomized Trial?" September 2013.

"Discussion of Meta-analysis of Ad5-vector HIV vaccine Trials" NIAID Mini-Summit on Adenovirus Platforms for HIV vaccines, September 2013.

"Vaccine Efficacy: An Overview" Keynote speaker for the Vaccines Subcommittee Program at the Annual Conference of the International Society for Clinical Biostatistics, August 2013.

"Statistical Issues in HIV Prevention Trials circa 2013" Workshop on Ethical Considerations Around Novel Combination Prevention Modalities in HIV Prevention and Vaccine Trials in Resource Limited Settings, April 2013

"Estimating the Burden of Pertussis in Mexican Adolescents from Paired Serological Data Using a Bivariate Mixture Model," University of Connecticut, October 2012.

"On the Design and Analysis of Clinical Trials with Correlated Outcomes" International Chinese Statistical Association Annual Meeting, June 2012.

"The Role of Statisticians at the NIH" ENAR Spring Meeting, March 2012

"Discussion of Adaptive Design in Vaccine Trials" ENAR Spring Meeting, March 2012.

"The effect of HIV-chemoprevention in compliers" Johns Hopkins University Causal Interest Group, December 2011

"Assessing Drug Safety Post Approval,Lessons from Vioxx, Avandia and Meridia, A Statistician's Perspective," American Heart Association Quality of Care and Outcomes Research Meeting, Washington DC, May 2011.

"Bounds on the effect of vaccine induced immune response on outcome," Workshop on Causal Inference in Health, Montreal, May 2011.

"Estimating the Burden of Pertussis in Mexican Adolescents," International Workshop on Pertussis in Adolescence: Controversies and Challenges, Mexico City April 2011.

"Analyzing the causal effect of immune response on protection in vaccine trials" University of Maryland Baltimore County Workshop on Contemporary Statistical Methods in Biostatistics March 2011.

"Immune Correlates Analysis From An Expanded HIV Vaccine Trial" WHO-UNAIDS Workshop: Adaptive Trail Design for HIV Vaccine Clinical Trials: Opportunities and Challenges, February 2011.

"Chop-Lump Tests for Vaccine Trials," International Biometric Society Meeting Brazil 2010.

"Strengths/Limitations of Different Clinical Sources of Evidence for Drug Safety in pharmacologic treatments of Type 2 DM - Controlled Clinical Trials, Observational Data, Meta-Analysis Synthesizing Information from Different Study Designs," FDA/Drug Information Agency Meeting on Development of Type 2 Diabetes Mellitus Drugs: State of the Art Cardiovascular Safety Assessments October 2010.

"Synthesizing Information from Different Study Designs," FDA Advisory Committee Meeting on Rosiglitazone (Avandia) July 2010.

"Chop-Lump Tests for Vaccine Trials," Harvard Department of Biostatistics/Merck Workshop May 2010.

'Crossover Trials for Survival and Recurrent Events" University of Pennsylvania, April 2010.

"Crossover Trials for Survival and Recurrent Events" Yakovlev Colloquim Speaker, University of Rochester, September 2009.

"Missing Data in Licensure Clinical Trials" National Academy of Sciences Workshop on the Handling of Missing Data in Clinical Trials September 2009.

"Successful Collaboration at the National Institute of Allergy and Infectious Diseases," Washington DC, Joint Statistical Meetings, August 2009.

"Collaborative Statistical Work at the National Institute of Allergy and Infectious Diseases" San Francisco, International Chinese Statistical Association, June 2009.

"Crossover Trials for HIV Prevention," Keystone Symposia Conference, Prevention of HIV/AIDS, Keystone Colorado, March 2009.

"Crossover Designs for Absorbing Binary Endpoints," George Mason University, February 2009.

"Crossover Designs for Absorbing Binary Endpoints," University of Alabama, September 2008.

"Chop-lump Tests for Vaccine Trials" WNAR, June 2008.

"Shared Random Parameter Models for Informative Missing Data," Graybill Conference, June 2008.

"Multiple Outputation: A Simple Fix for Complex Clustered Data," National Institute of Aging Workshop on Statistical Methods for Longitudinal Data, June 2007.

"The Burden of Success," Plenary address, HIV Vaccine Trials Network Annual Meeting, May 2007.

"Determining the Causal Role of Immunological Surrogates in Vaccine Trials," Workshop on Statistical and Epidemiology Issues in HIV Research, April 2007.

"On Comparing Infecteds in Vaccine Trials" ENAR Spring Meeting, March 2007.

"Designs to Assess the Role of Immune Response in Vaccine Trials" FDA, September 2006.

"Designs to Assess the Role of Immune Response in Vaccine Trials" ENAR Spring Meeting, March 2006.

"Designs to Assess the Role of Immune Response in Vaccine Trials" George Washington University, October 2005.

"Composite Endpoints," Future Clinical Trial Issues In Multiple Sclerosis, Washington DC, December 2004.

"An Independent Analysis of the Effect of Race in VAX004," Symposium speaker at the 11th Conference on Retroviruses and Opportunistic Infections, San Francisco, February 2004.

"An Analysis of VAX004," AIDS Vaccine Research Working Group, September 2003; Advisory Committee on Immunization Practices:HIV Vaccine Working Group, September 2003; HIV Communications Campaign Steering Committee, October 2003; Consultation Meeting on VAX004 Results, December 2003; 2004 African-Americans and AIDS Conference, February 2004; Office of AIDS Research Advisory Council, April 2004.

"New Designs to Assess the Role of Immune Response in Vaccine Trials,"Statistical Center for HIV/AIDS Research and Prevention, Fall 2003; Harvard Department of Biostatistics/Schering Plough Workshop, Spring 2004.

"Multiple Outputation: Inference for Complex Multivariate Data by Averaging Analyses From Univariate Data," Johns Hopkins University, Fall 2003; Yale University, Fall 2003; National Cancer Institute, Fall 2003.

"Regression Analysis Based on Pairwise Ordering of Patients' Clinical Histories," Emerging Issues in Longitudinal Data Analysis, Joint Summer Research Conference, Mt Holyoke College, Summer 2002; Northern Illinois University, Spring 2002.

"The Role of the DSMB at the National Institutes of Health," 2001 Biostatistics and Clinical Data Management Workshop: The Road Ahead to Drug Development in the 21st Century, sponsored by PHRMA, Fall 2001.

"Adaptive Modification of Sample Size in Clinical Trials: Discussant" Joint Statistical Meetings, Summer 2001.

"On the Effect of Treatment Among Treatment Compliers: An Analysis of the Multiple Risk Factor Intervention Trial," Joint Statistical Meetings, Summer 2000.

"On The Effect of Treatment Among Would-be Treatment Compliers," University of Pennsylvania, Fall 1999.

"Adaptively Changing Subgroup Proportions in Clinical Trials" Midwest Biopharmaceutical Society Workshop, Spring 1999.

"On the Effect of Treatment Among Treatment Compliers: An Analysis of the Multiple Risk Factor Intervention Trial," Columbia University, Division of Biostatistics, Spring 1999.

"Testing Treatment Efficacy in Clinical Trials of Opiate Addicts," Biometric Society (ENAR) Spring Meeting 1999.

"Valid Inference in Random Effects Meta-analysis," Biometric Society (ENAR) Spring Meeting 1999.

"On the Effect of Treatment Among Treatment Compliers," National Cancer Institute, February 1999.

"Valid Inference in Random Effects Meta-analysis," Food and Drug Administration, Fall 1998.

"Methods for Missing Data in Clinical Trials," Instructor, Society for Clinical Trials Meeting, Spring 1998.

"Repeated Probit Regression When Covariates Are Measured With Error," University of Rochester, Spring 1998.

"Analyzing Multiple Endpoints in Clinical Trials," Drug Information Agency, Hilton Head Spring Meeting 1997.

"Multivariate Tests in Clinical Trials," Biometric Society (ENAR) Spring Meeting 1996.

"Models for Informative Missing Binary Data," UCSF, September 1995.

"Multiple and Composite Endpoints In AIDS Clinical Trials," FDA Workshop on Current Issues in AIDS Clinical Trials, September 1995.

"Multiple Endpoints in Clinical Trials," Fourth Regional Symposium on the Design and Analysis of Clinical Trials, UCSF Graduate Programs, September 1995.

"Design Modifications in Ongoing Clinical Trials," Chair/Organizer, Joint Statistical Meetings Invited Session, August 1995

"Statistical Issues in HIV/AIDS Research Symposium," discussant, June 1995.

"Accounting for Covariates Observed Post Randomization for Discrete and Continuous Repeated Measures Data," discussant, Washington Statistical Society, May 1995.

"A Generalized Linear Model for Informative Missing Data," University of Maryland, November 1994.

"Dealing With Multiple Endpoints in Clinical Trials," Food and Drug Administration, August 1994.

"Composite Endpoints in Clinical Trials," discussant, Society for Clinical Trials Annual Meeting, May 1994.

"A Conditional Linear Model With Random Effects For Missing Data in Clinical Trials," Carnegie Mellon University, March 1994.

"An Approximate Generalized Linear Model for Informative Missing Data," Delaware Chapter of the American Statistical Association, February 1994.

"Statistical Implications of Different Clinical Investigation Designs for Antiarrhythmic Devices," Policy Conference on Clinical Investigation of Antiarrhythmic Devices, November 1993.

"Testing for Nonmonotone Dose Response Curves Using A Slope Process," National Cancer Institute, June 1993.

"Multivariate Tests for Multiple Endpoints," Biometric Society (ENAR) Spring Meeting 1993.

"Modeling Transitional and Joint Marginal Distributions in Repeated Categorical Data," NIH Conference on Current Topics in Biostatistics, January 1993.

"Semiparametric Methods For The Analysis of Dependent Response Data," discussant, Biometric Society (WNAR) Joint Statistical Meetings, August 1992.

"Monitoring Multi-Armed Trials With Pairwise Comparisons," Biometric Society (ENAR) Joint Statistical Meetings, August 1992.

"Selection Bias in Clinical Trials Using Random Permuted Blocks," Johns Hopkins University, November 1991.

"Issues in the Analysis of Clinical Trials for Opiate Dependence," Statistical Issues in Clinical Trials for Treatment of Opiate Dependence, November 1991.

"Determination of Normal Ranges For α-Antitrypsin Deficiency: A Statistical Model of an Upregulatable Gene," discussant, Washington Statistical Society, December 1990.

"Medical Decision Making and the ROC Curve: A Nonparametric Perspective," discussant, Washington Statistical Society, May 1990.

"The Effect of OPTEMPO on the Battle 'E' ," U.S. Navy Resources-to-Readiness Conference, November 1986.

CONTRIBUTED PRESENTATIONS

"Outputation Permutation: Exact Inference for Complex Clustered Data," Joint Statistical Meeting, August 2006.

"A Simple Permutation-Type Method for Testing Circular Uniformity with Correlated Angular Measurements," Biometric Society (ENAR) Spring Meeting 2000.

"An Approximate Generalized Linear Model With Random Effects For Informative Missing Data," Annual Meeting, American Statistical Association, 1992.

"Growth Curve Models Under Order Restrictions," Annual Meeting, American Statistical Association, 1990.

"Distinguishing Heterogeneity from Decreasing Hazard Rates," Annual Meeting, American Statistical Association, 1988.

INTERNAL REPORTS

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Follmann, DA "Should Radars Be Warmed Up?" CNA Research Memorandum 88-82, 1988.

Goldberg, M. & **Follmann, DA** "Numerical Methods in Maximum Likelihood Estimation," CNA Research Contribution 583.

Kostiuk, P. & **Follmann, DA** "The Retention of Navy Veterans in the Selected Reserve," CNA Research Memorandum 88-72, May 1988.

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Follmann, DA "The Effect of EM Manning on the Material Condition of the Electrical Distribution System," CNA Research Memorandum 87-225, November 1987.

Follmann, DA, Goldberg, M. & May, L. "Modeling Spikes in Hazard Rates," CNA Research Contribution 572, October 1987.

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