

# DEAN FOLLMANN

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## EDUCATION

1981-85 Carnegie Mellon University. Ph.D. in Statistics. Dissertation advisor, Dr. Diane Lambert. 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

Fellow of the American Statistical Association 2003.

NIH Merit Award 1993, 2008.

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 (Biostatistics) NIAID and Chief of the Biostatistics Research Branch. Head of a growing 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

Chair of the External 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 NCI, Spring 2008.

Member of the Board of Scientific Counsellors for the review of the Laboratory of Epidemiology, Demography, and Biometry, May 2008.

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

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-present.

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

Consulting Statistician, *Blood*, 1999-present.

Referee for *American Journal of Epidemiology*, *American Statistician*, *Annals of Statistics*, *Blood*, *Biometrics*, *Biometrika*, *Communications in Statistics*, *Epidemiologic Reviews*, *IEEE*

*Transactions on Information Theory, International Journal of Statistics and Management Systems, Journal of the American Statistical Association, Journal of Business and Economic Statistics, Journal of Biopharmaceutical Statistics, Journal of The Royal Statistical Society: Series B, Journal of Statistical Computation and Simulation, Psychological Bulletin, Psychometrika, and Statistics in Medicine.*

### **Data & Safety Monitoring Boards**

Member of the NHLBI INERMACS–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.

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

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**

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

**Follmann, D.A.** & Proschan M “Location testing with unknown correlation” *submitted*

**Follmann, D.A.**, Qin J, Hoshino Y. “Estimation of viral infection and replication in cells using convolution models,” *submitted*

Hu, Z, **Follmann, D.A.**, & Qin J “Nonparametric regression with dimension reduction for mean response estimation with missing data” *submitted*

Nason, M, **Follmann, D.A.** “Crossover trial designs for absorbing binary endpoints,” *Biometrics*, under revision.

**Follmann, D. A.** & Fay M, “Within Cluster Permutation: Exact Inference for Complex Clustered Data,” *under revision*

**Follmann D.A.**, Fay, M. & Proschan M.A. “Chop-lump tests for Vaccine Trials,” to appear *Biometrics*

Huang, CY, Qin, J, & **Follmann D.A.** “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 D.A.** “Semiparametric two-sample changepoint model with application to human immunodeficiency virus studies *JRSS-C: Applied Statistics* 57, Part 5, pp. 589607

Hu, Z, **Follmann D.A.**, 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* 27 (22) 4489-4501.

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

Brittain, E, **Follmann, D.A.**, & 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 D.A** & 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, D.A.** “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, D.A.** “Accounting for Variability in Sample Size Estimation with Applications to Nonadherence and Estimate of Variance and Effect Size,” *Biometrics* 2007; 63 465-474.
- Hu, Z., & **Follmann, D.A.** “Statistical Methods for Active Extension Trials,” *Statistics in Medicine* 2007; 26 2433-2448.
- Follmann, D. A.** “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 D.A**, 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, D. A.**, “A Permutation Approach to the Behrens-Fisher Problem,” *Journal of the Korean Statistical Society* 2004; 33 79-97.
- Stylianou, M. & **Follmann, D.A.** “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, D. A.**, & Lin, J.P. “A Statistical Method for Adjusting Covariates in Linkage Analysis with Sib Pairs,” *Biomed Central Genetics* 2003; 31; 4 Suppl 1:S51.
- Follmann, D. A.**, “Comparing HLA Antigen Frequencies Between Two Groups,” *Statistics in Medicine* 2003; 22 1999-2013.
- Follmann, D. A.**, 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, D.A.** “A Random Effects Transition Model for Longitudinal Binary Data with Informative Missingness,” *Statistica Neerlandica* 2003; 57 100-111.
- Follmann, D. A.**, “Regression Analysis Based on Pairwise Ordering of Patients’ Clinical Histories,” *Statistics in Medicine* 2002; 21 3353-3367.
- Albert, P.S. & **Follmann, D.A.**, 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, D. A.**, & Suh, E. “Parametric and Semiparametric Approaches to Testing for Seasonal Trend in Serial Count Data,” *Biostatistics* 2002; 289-298.
- Fay, M. P. & **Follmann, D. A.**, “Designing Monte Carlo Implementations of Permutation or Bootstrap Hypothesis Tests,” *American Statistician* 2002; 56 63-70.
- Hunsberger, S. & **Follmann, D.A.** “Testing for Treatment and Interaction Effects in Semiparametric Analysis of Covariance,” *Statistics in Medicine*, 2001; 20 1-19.
- Follmann, D.A.** “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, D.A.** “Modeling Repeated Count Data Subject to Informative Dropout,” *Biometrics*. 2000; 56 667-677.
- Follmann, D.A.** & Proschan, M.A., “A Multivariate Test of Interaction for Use in Clinical Trials,” *Biometrics*. 1999; 55 1151-1155.
- Follmann, D.A.** & Proschan, M.A., “Valid Inference in Random Effects Meta-analysis,” *Biometrics*. 1999; 55 732-737.
- Follmann, D.A.** & Proschan, M.A., “A Simple Permutation-Type Method for Testing Circular Uniformity with Correlated Angular Measurements,” *Biometrics*, 1999; 55 782-791.
- Follmann, D.A.** & Albert, P.S., “Bayesian Monitoring of Event Rates with Censored Data,” *Biometrics*, 1999; 55 603-607.
- Follmann, D.A.**, Hunsberger, S, & Albert, P.S. “Repeated Probit Regression When Covariates Are Measured With Error,” *Biometrics*, 1999; 55 403-409.
- Wu M., & **Follmann, D.A.** “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, D. A.** “Group Sequential Monitoring of Multi-Armed Clinical Trials,” *Drug Information Journal*, 1999; 33 479-486.
- Gu, M., **Follmann, D.A.**, & Geller, N. “Monitoring a General Class of Two Sample Survival Statistics with Applications,” *Biometrika*, 1999; 86 45-58.
- Follmann, D.A.** “Adaptively Changing Subgroup Proportions in Clinical Trials,” *Statistica Sinica*, 1997; 7 1085-1102.
- Albert, P.S. & **Follmann, D.A.**, Barnhart, H. X. “A Generalized Estimating Equations Approach for Modeling Multivariate Random Length Binary Data,” *Biometrics*, 1997; 53 1116-1124.
- Proschan, M. & **Follmann, D.A.** “A Restricted Test of Circadian Rhythm,” *Journal of the American Statistical Association* 1997; 92 717-724.
- Follmann, D.A.** “Long Term Followup in AIDS Clinical Trials: Discussion,” *Statistics in Medicine*, 1996; 15 2367-2370.
- Follmann, D.A.** “A Simple Multivariate Test for One Sided Alternatives,” *Journal of the American Statistical Association*, 1996; 91 854-861.
- Proschan, M. A. & **Follmann, D.A.** “One Experiment or Many? The Effect of a Single Control on the Distribution of Type I Errors,” *American Statistician*, 1995; 49 144-149.
- Follmann, D.A.** “Multivariate Tests for Multiple Endpoints in Clinical Trials,” *Statistics in Medicine*, 1995; 14 1163-1176.
- Geller, N., Proschan, M., & **Follmann, D. A.** “Group Sequential Monitoring of Multi-Armed Clinical Trials,” *Drug Information Journal*, 1995; 29 705-713.
- Follmann, D.A.** & Wu, M. “An Approximate Generalized Linear Model With Random Effects For Informative Missing Data,” *Biometrics*, 1995; 51 151-168.
- Proschan, M. A., **Follmann, D.A.** & Geller, N.L. “Monitoring Multi-Armed Trials,” *Sta-*

*tistics in Medicine*, 1994; 13 1441-1452.

**Follmann, D.A.**, Proschan, M. A. & Geller, N. L. "Monitoring Multi-Armed Trials," *Biometrics* 1994; 50 325-336.

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

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

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

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

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

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

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

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

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

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

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

## MEDICAL PUBLICATIONS

Lim JK, Lisco A, McDermott DH, Lisco, A, Foster GA, Krysztof D, **Follmann DA**, Stamer, SL, & Murphy, PM. "Large Scale Analysis of CCR5 Deficiency in West Nile Virus-Infected Blood Donors," submitted.

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*, to appear.

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, **Follman 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.

Catalfamo M, Di Mascio M, Hu Z, Srinivasula S, Thakera V, Adelsberger 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.

Melenhorst J, Lay M, Price D, Adams S, Zeilah J, Sosa E, Hensel N, **Follmann D.A.**, Douek D, Davenport M, Barrett J, "Relative contribution of T cell receptor-beta locus factors and HLA in the shaping of the mature human Vbeta repertoire," *Journal of Immunology* 2008; 180(10) 6484-6489.

Hoshino Y, Qin, J, **Follmann D**, Strauss, S, & Cohen J "The number of herpes simplex virus-infected neurons and the number of viral genome copies per neuron correlate with the latent viral load in ganglia," *Virology* 2008; 372 56-63.

Lopez-Granados E, Temmerman S, Wu L, Reynolds JC, **Follmann D**, Liu S, Rauch F, Jain A, "Osteopenia in X-linked Hyper-IgM syndrome reveals a regulatory role for CD40 ligand in osteoclastogenesis", *Proceedings of the National Academy of Sciences* 2007; 104; 5056-5061.

**Follmann D.A.**, Duerr A, Tabet S, Gilbert P, Moodie Z, Cardinalli M & Self, S. "Endpoints and Regulatory Issues in HIV Vaccine Clinical Trials: Lessons from a Workshop," *Journal of Acquired Immune Deficiency Syndrom* 2007; 44; 49-60.

Mavilio D, Lombardo G, Kinter A, Fogli M, La Sala A, Ortolano S, Farschi A, **Follmann, D.A.**, Gregg R, Kovacs C, Marcenaro E, Pende D, Moretta A, Fauci A "Characterization of the defective interaction between a subset of natural killer cells and dendritic cells in HIV-1 infection," *Journal of Experimental Medicine*, 2006; 203 (10) 2339-2350.

Kim Yea-Jean, Kumaraswami V, Choi Eun Hwa, Mu JB, **Follmann D.A.**, Zimmerman P, Nutman TB, " Genetic polymorphisms of eosinophil-derived neurotoxin and eosinophil cationic protein in tropical pulmonary eosinophilia," *American Journal of Tropical Medicine and Hygiene* 2005; 73 (1): 125-130.

Malaspina, A., Moir, S., Orsega, S., Vasquez, J., Miller, N., Donoghue, E., Kottlil, S., Gezmu, M., **Follmann D.A.**, Galina, M., Vodeiko, G., Levandowski, R., Mican, J., & Fauci, A. "Compromised B Cell Responses to Influenza Vaccination in HIV-Infected Individuals,"



*Journal of Infectious Diseases* 2005; 191 1442-1450.

Gilbert PB, Peterson ML, **Follmann D.A.**, Hudgens MG, Francis DP, Gurwith M, Heyward WL, Jobes DV, Popovic V, Self SG, Sinangil F, Burke D, & Berman PW. "Correlation between Immunologic Responses to a Recombinant Glycoprotein 120 Vaccine and Incidence of HIV-1 Infection in a Phase 3 HIV-1 Preventive Vaccine Trial," *Journal of Infectious Diseases* 2005; 191 666-677.

Mavilio, D., Lombardo, G., Benjamin, J., Kim, D., **Follmann, D.A.**, Marcenaro, E., Planta, M., Turney J., Kovacs, C., Moretta, A. & Fauci, A.S. "Characterization of CD56neg/CD16pos Natural Killer Cells: a Highly Dysfunctional NK Subset expanded in HIV infected viremic individuals," *Proceedings of the National Academy of Sciences*, 2005; 102 (8): 2886-2891.

Di Mascio M, Markowitz M, Louie M, Hurley A, Hogan C, Simon V, **Follmann D.A.**, Ho DD, Perelson AS "Dynamics of intermittent viremia during highly active antiretroviral therapy in patients who initiate therapy during chronic versus acute and early human immunodeficiency virus type 1 infection," *Journal of Virology* 2004; 78 (19): 10566-10573.

Nakamura, R., Battiwalla, M., Solomon, S., **Follmann, D.A.**, Chakrabarti, S., Cortez, K., Hensel, N., Childs, R., % Barrett, J. "Persisting posttransplantation cytomegalovirus antigenemia correlates with poor lymphocyte proliferation to cytomegalovirus antigen and predicts for increased late relapse and treatment failure," *Biology of Blood and Marrow Transplantation* 2004; 10 49-57.

Sereti, I., Anthony, K., Martinez-Wilson, H., Lempicki, R., Adelsberger, J., Metcalf, J., Hallahan, C., **Follmann D.A.**, Davey, R., Kovacs, J., Lane, H.C. "IL-2induced CD4+ T-cell expansion in HIV-infected patients is associated with long-term decreases in T-cell proliferation," *Blood*, 2004; 104 775 - 780.

Farel, C., Chaitt, D., Hahn, B., Tavel, J., Kovacs, J., Polis M., Masur, H., **Follmann D.A.**, Lane, H.C., Davey, R. "Induction and maintenance therapy with intermittent interleukin-2 in HIV-1 infection," *Blood*, May 2004; 103 3282 - 3286.

Kuramoto, K., **Follmann D.A.**, Hematti1, P., Sellers, S., Laukkanen, M. Seggewiss, R., Metzger, M., Donahue, Krouse, A., Donahue, R., von Kalle, C., Dunbar, D. "The impact of low-dose busulfan on clonal dynamics in nonhuman primates," *Blood* 2004; 104 1273-1280.

Kuramoto, K., **Follmann D.A.**, Hematti1, P., Sellers, S., Agricola, B., Metzger, M., Donahue, R., von Kalle, C., Dunbar, D. "The Impact of Chronic Cytokine Therapy on Clonal Dynamics in Non-Human Primates," *Blood* 2004; 103 4070-4077.

Rosenfeld, S., , **Follmann, D.A.**, Nunez, O., & Young, N. "Anti-Thymocyte Globulin and Cyclosporine for Severe Aplastic Anemia: Robust Hematologic Responses Predict Outcome," *Journal of the American Medical Association* 2003; 289 1130-1135.

"A comparative analysis of the results from 4 trials of beta-blocker therapy for heart failure: BEST, CIBIS-II, MERIT-HF, and COPERNICUS," Domanski MJ, Krause-Steinrauf H, Massie BM, Deedwania P, **Follmann D**, Kovar D, Murray D, Oren R, Rosenberg Y, Young J, Zile M, Eichhorn E *Journal of Cardiac Failure*, 2003; 9 354-363.

Stroncek, D. Shawker, T. **Follmann, D.A.**, & Leitman, S. "G-CSF-Induced Spleen Size Changes in Peripheral Blood Stem Cell Donors," *Transfusion* 2003; 43 (5): 609-613.

Domanski, M. Krause-Steinrauf, H., Deedwania, P., **Follmann D.A.**, Ghali, J., Gilbert, E. Haffner, S., Katz, R., Lindenfeld, J., Lowes, B., Martin, W., McGrew, F., Bristow, M., "The Effect of Diabetes on Outcomes of Advanced Heart Failure Patients in the BEST Trial," *Journal of the American College of Cardiology* 2003; 42 914-922.

Melenhorst, J. Eniafe, R. **Follmann, D.A.**, Nakamura, R. Kirby, M., & Barrett, J "Molecular and Flow Cytometric Characterization of the CD4 and CD8 T Cell Repertoire in Patients with Myelodysplastic Syndrome," *British Journal of Haematology* 2002; 119 97-105.

Sloand, E., Kim, S., Maciejewski, J., Tisdale, J., **Follmann, D. A.**, Young, N.S. "Intracellular Interferon-Gamma in Circulating and Marrow T Cells Detected by Flow Cytometry and the Response to Immunosuppressive Therapy in Patients with Aplastic Anemia," *Blood* 2002; 100 1185-1191.

Stroncek, D. Matthews, D. **Follmann, D.A.**, & Leitman, S. "Kinetics of G-CSF Induced Granulocyte Mobilization in Healthy Subjects: Effects of Route of Administration and Addition of Dexamethasone," *Transfusion* 2002; 42 597-602.

Maciejewski, J.P., **Follmann, D.A.**, Nakamura, R., Sauntharajah, Y., Rivera, C. E., Simonis, T., Brown, K.E., Barrett, J.A., & Young, N.S. "Increased Frequency of HLA-DR2 in Patients with Paroxysmal Nocturnal Hemoglobinuria and the PNH/Aplastic Anemia Syndrome," *Blood* 2001; 98 3513-3519.

The BEST Investigators, "A Trial of the Beta-Blocker Bucindolol in Patients with Advanced Chronic Heart Failure," *The New England Journal of Medicine*, 2001; 344 1659-1667.

Exner, D.V., Pinski, S. L, Wyse, G., Renfroe, E. G. **Follmann, D. A.**, Gold M., Beckman, K., Coromilas, J., Lancaster, S., & Hallstrom, A.P. "Electrical Storm and Mortality In Patients: A Retrospective Analysis of the Antiarrhythmic Versus Implantable Defibrillators (AVID) Trial," *Circulation*, 2001; 2066-2071.

**Follmann, D.A.** & Schron E. "Essentials of Randomized Clinical Trials," *Pacing and Clinical Electrophysiology*, 2001; 24 254-259.

Hallstrom, A.P, McAnulty, J., Wilkoff, B. **Follmann D.A.**, Raitt, M., Carlson, M., Gillis, A.M., Shih, H-T, Powell, J., Duff, H., Halperin, B. "Patients at Lower Risk of Arrhythmia Recurrence: A Subgroup in Whom Implantable Defibrillators May Not Offer Benefit," *Journal of the American College of Cardiology*, 2001; 37 1093-1099.

Connolly, S.J., Hallstrom, A. P., Cappato, R., Schron, E.B., Kuck, K.H., Zipes, D., Greene, H.L., Domanski, M., **Follmann D.A.**, Gent, M., & Roberts, R.S. "Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials," *European Heart Journal* 2000; 21:(24) 2071-2078.

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## ECONOMICS PUBLICATIONS

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## BOOK REVIEWS

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## BOOK CHAPTERS

Albert P. S. & **Follmann, D.A.** "Shared Random Effects Models" to appear in *Longitudinal Data Analysis: A Handbook of Modern Statistical Methods*, Chapman & Hall/CRC Press

**Follmann, D.A.** "Primary Efficacy Endpoint," to appear in *Encyclopedia of Clinical Trials*, John Wiley & Sons

**Follmann, D.A.** "Subgroups and Interactions," in *Advances in Clinical Trial Biostatistics* N. Geller editor. Marcel Dekker 2004.

Geller, N. L., Leifer, E. S., **Follmann, D.A.**, & Carter, S "Design of Early Trials in Stem Cell Transplantation: A Hybrid Frequentist-Bayesian Approach," in *Advances in Clinical Trial Biostatistics* N. Geller editor. Marcel Dekker 2004.

**Follmann, D.A.**, Wu, M., & Geller, N. "Issues in the Analysis of Clinical Trials for Opiate Dependence," *Statistical Issues in Clinical Trials for Treatment of Opiate Dependence* 1992; National Institute of Drug Abuse: Monograph 128.

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## INVITED PRESENTATIONS

"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  $\alpha$ -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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CONFIDENTIAL. CNA Research Memorandum, 1988.

Kostiuk, P., **Follmann, D.A.** & Shiells M. "Utilization of Personnel Resources within the Navy Selected Reserve," CNA Research Memorandum 88-155, 1988.

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

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

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

**Follmann, D.A.** "The Effect of Reliability Centered Maintenance on Ship Readiness," CONFIDENTIAL. CNA Research Memorandum 88-40, March 1988.

Kostiuk, P. & **Follmann, D.A.** "Learning Curves, Personal Characteristics, and Job Performance," CNA Research Contribution 584, March 1988.

Kostiuk, P. & **Follmann, D.A.** "Naval Reserve Recruiter Experience and Productivity," CNA Research Memorandum 87-240, December 1987.

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

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

**Follmann, D.A.** "Modeling Failures of Intermittently Used Machines," CNA Research Memorandum 87-111, July 1987.

**Follmann, D.A.** "The Effect of a Ship's Employment History on the Material Condition Index," CNA Research Memorandum 87-36, May 1987.

**Follmann, D.A.** & Goldberg, M. "Distinguishing Heterogeneity from Decreasing Hazard Rates," CNA Research Memorandum 86-260, December 1986.

**Follmann, D.A.** "An Analysis of 4855 Data: Combat System Availability Estimates and the Effect of Usage on Failures," CNA Research Memorandum 86-215, October 1986.

**Follmann, D.A.** & Goldberg, M. "Beta-Geometric Model for Aircraft Component Failures," CNA Research Memorandum 86-202, September 1986.

**Follmann, D.A.** "The Battle Force Logistics Coordinator in FLEETEX 1-86," CNA Research Memorandum 86-147, October 1986.

**Follmann, D.A.** "A Comparison of Two Models for Component Failures," CNA Research Memorandum 86-138, June 1986.

**Follmann, D.A.**, Marcus, A., & Cavalluzzo, L. "OPTEMPO and Ship Readiness," CNA Research Memorandum 86-123, June 1986.

**Follmann, D.A.** "Predicting Occupational Choices of Air Force Enlisted Personnel," RAND Working Draft WD(L)-2384-AF, October 1984.