Milken Institute School of Public Health

THE GEORGE WASHINGTON UNIVERSITY

April 4, 2026

John M. Lachin, III, Sc.D.
Research Professor of Biostatistics and Bioinformatics, and of Statistics
Department of Biostatistics and Bioinformatics, Milken Institute School of Public Health.
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1) **Personal Data**

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2) **Education and Training**

a) Undergraduate Education
B.S., Psychology (Experimental), Tulane University, 6/65

b) Graduate Education
Sc.D., Biostatistics, University of Pittsburgh, 9/69-4/72

3) **Professional Employment**

1972-1973 Mental Hygiene Epidemiologist and Director, Division of Program Information and Evaluation, Virginia State Department of Mental Health and Mental Retardation, Richmond; and Adjunct Assistant Professor, Department of Biometry, Medical College of Virginia, Health Sciences Division, Virginia Commonwealth University.
1973-1977 Assistant Research Professor of Statistics, The Biostatistics Center, GWU
1977-1982 Associate Research Professor of Statistics, The Biostatistics Center, GWU
1982-1984 Research Professor of Statistics, The Biostatistics Center, GWU
1984-2002 Professor of Statistics (tenure 1987), The Biostatistics Center and Department of Statistics, GWU
2002-2014 Professor of Biostatistics and Epidemiology, and of Statistics (joint), with tenure, The Biostatistics Center, Department of Epidemiology and Biostatistics, and Department of Statistics.
2014 - 2019 Research Professor of Biostatistics and Epidemiology, and of Statistics (joint), The Biostatistics Center, Department of Epidemiology and Biostatistics,
2019 - 2024 Research Professor of Biostatistics and Bioinformatics, and of Statistics (joint), The Biostatistics Center, Department of Biostatistics and Bioinformatics. GWU. Milken Institute School of Public Health.

2024 - Emeritus Professor of Biostatistics and Bioinformatics, and of Statistics (joint), The Biostatistics Center, Department of Biostatistics and Bioinformatics. GWU. Milken Institute School of Public Health

1980-1985 Assistant Director, The Biostatistics Center, GWU
1985-1988 Co-Director, The Biostatistics Center, GWU
1988-2000 Director, The Biostatistics Center, GWU
2001-2010 Co-Director, The Biostatistics Center, GWU
2010-2012 Interim Director, The Biostatistics Center, GWU.

Teaching Responsibilities:

- Currently not teaching. Taught 1-2 graduate courses per year during 1979-2006. See Section 13 for list of courses taught.

Administrative Responsibilities

- Former Director of the Biostatistics Center, a research facility of the University with 115 employees and total funding of $60 million annually.

- Program Director for Biostatistics and Chair of the Executive Committee for the graduate degree program in Biostatistics and Epidemiology, jointly administered by the Department of Epidemiology and Biostatistics and the Department of Statistics, 1995 - 2004.

Research Responsibilities (current only)

- Formerly Principal Investigator and Director (1982-2020), now Co-investigator (2020 -), of the Data Coordinating Center for the study of the *Epidemiology of Diabetes Intervention and Complications* (EDIC), a long-term epidemiologic study of 1441 subjects with Type 1 diabetes originally enrolled in the *Diabetes Control and Complications Trial* (DCCT/EDIC), funded by the National Institute of Diabetes, Digestive and Kidney Diseases. Initiated in 1982. Current funding to July, 2027. Co-Principal Investigators Barbara Braffett and Ionut Bebu
- Formerly Principal Investigator and Director (2012 – 2022), now Co-Investigator (2022 -) of the Coordinating Center for the *Glycemia Reduction Approaches for Diabetes: A Comparative Effectiveness Study* (GRADE). A long-term randomized trial, funded by the National Institute of Diabetes, Digestive and Kidney Diseases. Initiated in 2010 with a planning grant. Current funding to 2026.

4) **Honors and Awards:**

- Tulane University Outstanding Alumni – Professional Excellence Award, School of Science and Engineering, April, 2024
- Fifty Year Faculty Anniversary Award, the George Washington University, April 23, 2024
- Top 10 Clinical Research Achievement Award. Clinical Research Forum. April 2023. For the GRADE Study. John Lachin Contact Principal Investigator.

- Distinguished Alumni Award for Research. University of Pittsburgh School of Public Health, December 2022
- Lifetime Achievement Award, 25th Anniversary Celebration of the George Washington University Milken Institute School of Public Health, October, 2022.
- Co-recipient with Barbara Braffett and Ionut Bebu, 2020 American Diabetes Association Michaela Modan Memorial Award, presented by the Public Health & Epidemiology Interest Group.
- Second Annual Robert F. Woolson Lecture, Department of Biostatistics, College of Public Health, University of Iowa, 2011.
- 2010 Oscar and Shoshana Trachtenberg Prize for Scholarship, The George Washington University, May, 2010.
- 2010 Distinguished Researcher Award, The George Washington University Medical Center, March, 2010.
- Inaugural Fellow, Society for Clinical Trials, 2006
- American Association of Publishers award for "The Outstanding Professional And Scholarly Title Of 2002 In Mathematics And Statistics" for the book co-authored with W. Rosenberger entitled *Randomization in Clinical Trials: Theory and Practice,* John Wiley and Sons, 2002.
- President, Society for Clinical Trials, 2002-3
- Joseph Ciminera Lecture, Merck and Company, 2002
- John C. Forbes Graduate Student Honors Colloquium. Medical College of Virginia, 1995
- The Charles H. Best Medal for Distinguished Service in the Cause of Diabetes. Awarded to the Diabetes Control and Complications Trial Research Group (J. Lachin, Principal Investigator and Director, Data Coordinating Center). American Diabetes Association, 1994.
- Elected Member, International Statistical Institute, 1993
- Distinguished Graduate Award, Graduate School of Public Health, University of Pittsburgh, 1992
- Delta Omega National Honor Society, 1991
- Elected Fellow, Royal Statistical Society, 1991
- Elected Fellow, American Statistical Association, 1989

5) Current (Recent) Grant Support

Total funding: $471,569,626 since 1985, no records prior to 1985.

- *Glycemia Reduction Approaches for Diabetes Effectiveness: A Comparative Effectiveness Study (GRADE)* 07/2017 – 07/2022, P.I., Coordinating Center, NIDDK Cooperative Agreement 1 U01 DK-098246, $115,406,642.

  Main Objective: To compare the effectiveness and safety of 4 commonly used anti-hyperglycemic agents, when added to metformin, for maintenance of metabolic homeostatis in 5000 recently diagnosed participants with type II diabetes over a minimum of 5 years of follow-up.

- *Epidemiology of Diabetes Intervention and Complications*: 7/2017 - 04/2022, P.I., Coordinating Center, NIDDK Grant U01-DK094176-02, $15,998,739. Current Co-P.I.s Barbara Braffett and Ionut Bebu

  Main Objective: To assess the role of the level of glycemia on the risk of micro and macro-vascular complications, cardiovascular disease and mortality in a cohort of 1200 survivors of a cohort of 1441 participants originally enrolled into the Diabetes Control and Complications Trial (1983-1993).

6) **Grants Concluded as Principal Investigator (P.I. or Co-P.I.)**

- *Glycemia Reduction Approaches for Diabetes Effectiveness: A Comparative Effectiveness Study (GRADE)*
  - 09/2012 – 06/2017, P.I., Coordinating Center, NIDDK Cooperative Agreement 1 U01 DK-098246, $134,184,766.
  - 09/2010 - 08/2012, P.I. Statistical Center, Subcontract from Mass. General Hospital under grant U34-DK-088043 from NIDDK. $437,178.
- *Epidemiology of Diabetes Intervention and Complications*:
  - 8/2012 - 06/2017, P.I., Coordinating Center, NIDDK Grant U01-DK094176-01, $14,000,778.
  - 4/1996 – 8/2012, P.I., Coordinating Center, NIDDK Contract N01-DK-6-2204, $44,401,926
- *Type 1 Diabetes TrialNet:* 09/29/2001 - 06/30/2010, Coordinating Center (2001-2008), Analysis Center (2008-2010), P.I., NIDDK Cooperative Agreement 1 U01 DK61055-01. $93,180,850.
- *Diabetes Prevention Program* - 7/94-6/2003, Co-P.I. 1994-1996 (Dr. Raymond Bain, Co-P.I.) and 1999-2002 (Dr. Sarah Fowler, Co-P.I.), Coordinating Center, NIDDK Cooperative Agreement No. 5-U01-DK48489. $23,224,129 during years as Co-PI.
- *Statistical Methods for Cancer Clinical Trials:* 9/97-8/2000, P.I., NCI Grant 2R01-CA-55098-04A2. $563,240.
- *Diabetes Control and Complications Trial*: 2/82-2/98, P.I., Coordinating Center, NIDDK Contract N01-AM-2-2206B. $29,448,712
- *Statistical Methods for Chronic Disease Clinical Trials*: 7/88-6/91, P.I., NIDDK Grant R01- DK35952. $110,461.
- *Study of Angiotensin Converting Enzyme Inhibition in Diabetic Nephropathy:* 12/86 - 9/92, (P.I. 1986-10/88; Co-P.I. 10/88 - 9/92) Biostatistical Coordinating Center, co-funded by Grant from E.R. Squibb and Sons, and NIDDK Grant R01-DK-39826. $304,865.
- *Collaborative Study of the Treatment of Lactic Acidosis with Dichloroacetate*: 4/86-3/92, Co-P.I. (Dr. Elizabeth Wright, P.I.), Data Coordinating Center, subcontract to NIDDK Grant R01-DK-35448 (Dr. Peter Stacpoole, P.I., University of Florida).
- *Lupus Nephritis Collaborative Study*: 4/81-6/88, P.I., Biostatistical Coordinating Center, NIDDK Grant R01-AM27769-02. $307,340.

- *New Drug Application for Ursodeoxycholic Acid:* 2/84-2/86, P.I., Biostatistical Unit, contract from Interstate Drug Exchange in collaboration with Garvey Associates, Inc.
- *Bile Acid Metabolism and Liver Injury In Gallstone Patients*: 4/83-9/85, P.I., Biostatistical Support Unit, Consortium Agreement under NIADDK Grant R01-AM31461 (Dr. Alan F. Hofmann, University of California at San Diego, Principal Investigator).
- *National Cooperative Gallstone Study*: 9/73-1/84, (P.I. effective 9/80) Biostatistical Support Unit, subcontract to NIADDK Contract N01-AM-0-2205. (Dr. Leslie J. Schoenfield, P.I., Cedars Sinai Medical Center).
- *Others*: Principal Investigator, contracts from other pharmaceutical companies for analyses of phase II and phase III clinical trials. Co-investigator for other NIH grants and contracts.

7) **Publications (5 books, 399 refereed papers, 30 non-refereed papers/chapters)**

Bibliometrics

Overall summary

	Refereed	Non-refereed	Total
Statistical	77	18	95
Medical	333	12	345
Total	410	30	440

5 books

Per Google Scholar as of February 16, 2024: H-Index is 101, i10 Index is 233, with 103,576 Citations.

Per a 2020 report from the Meta-Research Innovation Center at Stanford University (METRICS), among 8 million authors world-wide since 1960, the number of citations to Dr. Lachin's work was ranked at the 99.94th percentile over his career, or in the top 6/100th of a percent, in the fields of Endocrinology & Metabolism, Clinical Medicine, and Statistics & Probability.

Per the Exaly Search Engine 02/24/2023

Most cited author in *Contemporary Clinical Trials* (1981, 1988)
Most cited paper in *Contemporary Clinical Trials* (1981, 1988)
Most published author in *Contemporary Clinical Trials* (1988, Lifetime)
Most cited author in *The New England Journal of Medicine* (2002)
Most cited paper in *The New England Journal of Medicine* (2002, 2015)
Most cited author in *Gastroenterology* (1982)
2nd most published author in *Diabetes Care* (2019)
3rd most published author in *Diabetes Care* (2017, 2018)

a) Articles in Refereed Journals (397 total)

Methodological (77 papers)

Sandoval GJ, Bebu I, Lachin JM. Cost-efficient multiply matched case-control study designs. Am J Epidemiol 2022, 191(11):1970-74

Sandoval GJ, Bebu I, Lachin JM. Cost-efficient clinical studies with continuous time survival outcomes. *Statistics in Medicine*. 2021;40:3682–3694. https://doi.org/10.1002/sim.8992

Lachin JM. Worst-Rank Score Methods—A Nonparametric Approach to Informatively Missing Data. *JAMA*. 2020 Oct 27;324(16):1670-1. doi:10.1001/jama.2020.7709

Lachin JM. Nonparametric Statistical Analysis. *JAMA.* 2020;323(20):2080–2081. doi:10.1001/jama.2020.5874

Bebu I, Braffett BH, Lachin JM. The minimum intensity of a mixed exposure that increases the risk of an outcome. Statistics in Medicine. 2020;1–9. https://doi.org/10.1002/sim.8705

Lachin JM, Bebu I. Braffett B. Models to assess the association of a semi-quantitative exposure with outcomes. *Am J Epidemiol* 2020, 189(12): 1573–1582, https://doi.org/10.1093/aje/kwaa071

Lachin JM, Nathan DM, Zinman B, Bebu I. Comment on Miller and Orchard: Understanding Metabolic Memory: A Tale of Two Studies. Diabetes 2020;69:291-299. *Diabetes*. 2020;69(7):e7-e8. doi:10.2337/db20-0311

Lachin JM, Bebu I. Closed testing of each group versus the others combined in a multiple group analysis. Clinical Trials 2020, Vol. 17(1) 77–86 DOI: 10.1177/1740774519879932

Lachin JM, Bebu I, Larsen MD, Younes N (2019) Closed testing using surrogate hypotheses with restricted alternatives. PLoSONE 14(7):e0219520. https://doi.org/10.1371/journal.pone.0219520

Bebu I, Lachin JM. Properties of composite time to first event versus joint marginal analyses of multiple outcomes. *Statistics in Medicine*. 2018; 37:3918-30. https://doi.org/10.1002/sim.7849

Bebu I, Lachin JM. Optimal screening schedules for disease progression with application to diabetic retinopathy. *Biostatistics*. 2018;19(1):1-13. doi.org/10.1093/biostatistics/kxx009.

Dickersin K, Dixon D, Ferris F, Goldberg J, Kimmel S, and Lachin JM. University of Pennsylvania 10th annual conference on statistical issues in clinical trials: Current issues regarding data and safety monitoring committees in clinical trials (afternoon panel session)**.** *Clinical Trials*, 2017, 15(4): 366 – 385. doi.org/10.1177/1740774518781849

Bebu I, Mathew T and Lachin JM. Probabilistic measures of cost-effectiveness. *Statistics in Medicine*. 2016, 35(22): 3976-3986. DOI 10.1002/sim.6987.

Bebu I and Lachin JM. Large sample inference for a win ratio analysis of a composite outcome based on prioritized components. *Biostatistics*, 2016, 17(1):178-87.

Lachin JM. Fallacies of last observation carried forward analyses. *Clinical Trials*, 2016, 13(2), 161-68 doi: 10.1177/1740774515602688. PMC4785044.

Lachin JM and Bebu I. Application of the Wei–Lachin multivariate one-directional test to multiple event-time outcomes. *Clinical Trials*, 2015, 12: 627-33.

Ma, Y., Lai, Y., Lachin, J.M. Identifying change points in a covariate effect on time-to-event analysis with reduced isotonic regression. (2014) *PLoS ONE*, 9 (12), art. no. A506.

Lachin JM. Applications of the Wei-Lachin multivariate one-sided test for multiple outcomes on possibly different scales *PLoS ONE,* 2014; 9(10): e108784.

Sun W, Larsen MD, Lachin JM. Methods for a longitudinal quantitative outcome with a multivariate Gaussian distribution multi-dimensionally censored by therapeutic intervention (2014) *Statistics in Medicine*, 33:. 1288-1306.

Lachin JM. Sample size and power for a logrank test and Cox proportional hazards model with multiple groups and strata, or a quantitative covariate with multiple strata. *Statistics in Medicine* 2013; 32:4413–4425. DOI: 10.1002/sim.5839.

Lachin JM. Reminiscences of Jerry Cornfield. *Clinical Trials* 2013; 10:337-339. DOI: 10.1177/1740774513477932.

Lachin JM. Power of the Mantel–Haenszel and other tests for discrete or grouped time-to-event data under a chained binomial model. *Statistics in Medicine* 2013; 32:220–229. DOI: 10.1002/sim.5480.

Lachin JM. Power and sample size evaluation for the Cochran-Mantel-Haenszel mean score (Wilcoxon rank sum) test and the Cochran-Armitage test for trend. *Statistics in Medicine* 2011; 30:3057-66. DOI: 10.1002/sim.4330.

Lachin JM. Futility interim monitoring with control of type I and II error probabilities using the interim Z-value or confidence limit. *Clinical Trials*, 2009, 6:565-573.

Lachin JM. Sample size evaluation for a multiply matched case–control study using the score test from a conditional logistic (discrete Cox PH) regression model. *Statistics in Medicine* 2008; 27:2509–2523. Correction. *Statistics in Medicine*. 2018;1–2.

Lachin JM, Younes N. A composite design for transition from a preliminary to a full-scale study. *Statistics in Medicine*. 2007; 26:5014-32.

Sparling YH, Younes N, Lachin JM, and Bautista OM. Parametric survival models for interval-censored data with time-dependent covariates. *Biostatistics* 7, 599-614, 2006.

Lachin JM. Operating characteristics of sample size re-estimation with futility stopping based on conditional power. *Statistics in Medicine*, 25, 3348-65, 2006.

Lachin JM. Maximum Information Designs. *Clinical Trials*, 2, 453-464, 2005.

Lachin JM. A review of methods for futility stopping based on conditional power. *Statistics in Medicine*, 24, 2747-2764, 2005.

Lachin JM. The role of measurement reliability in clinical trials. *Clinical Trials*, 1, 553 – 566, 2004.

Dickersin K, Davis BR, Dixon DO, George SL, Hawkins BS, Lachin JM, Peduzzi P, Pocock S. The Society for Clinical Trials supports United States legislation mandating trials registration. *Clinical Trials*, 1, 417-420, 2004.

Lachin JM. Conflicts of interest in data monitoring of industry versus publicly financed clinical trials. *Statistics in Medicine*, 23, 1519-1521, 2004.

Lachin JM, Greenhouse SW, Bautista OM. Group sequential large sample T^2-like χ^2 tests for multivariate observations. *Statistics in Medicine*, 22, 3357-3368, 2003.

Lan KKG, Lachin JM, and Bautista OM. Over-ruling a group sequential boundary - a stopping rule versus a guideline. *Statistics in Medicine*, 22, 3347-3355, 2003.

Lachin, JM. A tribute to Samuel W. Greenhouse. *Statistics in Medicine*, 22, 3267-3276, 2003.

Hu MX and Lachin, JM. Corrections for Bias in Maximum Likelihood Parameter Estimates Due to Nuisance Parameters. *Communications in Statistics*, 32, 619-639, 2003.

Hu M and Lachin JM. Application of robust estimating equations to the analysis of quantitative longitudinal data, *Statistics in Medicine*, 20, 3411-3428, 2001.

Bautista OM, Bain RP and Lachin JM. A flexible stochastic curtailing procedure for the log-rank test. *Controlled Clinical Trials*, 21, 428-439, 2000.

Lachin JM. Statistical Considerations in the Intent-to-treat Principle. *Controlled Clinical Trials*, 21, 167-189, 2000.

Lachin JM. Worst-rank score analysis with informatively missing observations in clinical trials. *Controlled Clinical Trials*, 20, 408-422, 1999.

Younes N and Lachin JM. Link-based models for survival data with interval and continuous time censoring. *Biometrics*, 53, 1199-1211, 1997.

Lachin JM. Group sequential monitoring of distribution-free analyses of repeated measures. *Statistics in Medicine*, 16, 653-668, 1997.

Lachin JM. Distribution-Free marginal analysis of repeated measures. *Drug Information Journal*, 30, 1017-1028, 1996.

Lan KKG and Lachin JM. Martingales without tears. *Lifetime Data Analysis*, 1, 361-375, 1995.

Rosenberger WF, Lachin JM, and Bain RP. Nonparametric test of stochastic ordering for multiple longitudinal measures. *Journal of Biopharmaceutical Statistics*, 5, 235-243,1995.

Lan KKG, Rosenberger WF and Lachin JM. Sequential monitoring of survival data with the Wilcoxon statistic. *Biometrics*, 51,1175-1183,1995.

Rosenberger WF and Lachin JM. The use of response-adaptive designs in clinical trials. *Controlled Clinical Trials*, 14, 471-484, 1993.

Lan KKG, Rosenberger WF, Lachin JM. Use of spending functions for occasional or continuous monitoring of data in clinical trials. *Statistics in Medicine*, 12, 2219-2231, 1993.

Palesch YY and Lachin JM. Asymptotically distribution-free multivariate rank tests for multiple samples with partially incomplete observations. *Statistica Sinica*, 4, 373-387, 1994.

Su JQ and Lachin JM. Group sequential distribution-free methods for the analysis of multivariate observations. *Biometrics*, 48, 1033-1042, 1992.

Lachin JM. Power and sample size evaluation for the McNemar test with application to matched case-control studies. *Statistics in Medicine*, 11, 1239-1251, 1992.

Lachin JM, Lan SP and the Lupus Nephritis Collaborative Study Group. Termination of a clinical trial with no treatment group difference: The Lupus Nephritis Collaborative Study. *Controlled Clinical Trials*, 1992, 13, 62-79

Lachin JM. Some large sample distribution-free estimators and tests for multivariate partially incomplete data from two populations. *Statistics in Medicine*, 11, 1151-1170, 1992.

Lan KKG and Lachin JM. Group sequential logrank tests in a maximum duration trial. *Biometrics*, 1990, 46, 759-770.

Wei LJ, Su JQ and Lachin JM. Interim analyses with repeated measurements in a sequential clinical trial. *Biometrika*, 1990, 77, 359-64.

Colton T, Greenhouse SW, Zelen M, Gehan EA, DeMets D, Ware JH, Gordon T, Lachin JM, Wittes J. Remembrances of Max Halperin. *Statistics In Medicine*, 1990, 9: 863-870 (1990). https://doi.org/10.1002/sim.4780090802

Lachin J, Gordon T, Greenhouse S, Lan KK, Wittes J. In memoriam: Max Halperin (1917-1988). *Controlled Clinical Trials*. 1988 9:170-172. DOI: 10.1016/0197-2456(88)90041-4. PMID: 3293910.

Lachin JM. Properties of randomization in clinical trials: Foreword. *Controlled Clinical Trials*, 1988, 9, 287-288.

Lachin JM. Statistical properties of randomization in clinical trials. *Controlled Clinical Trials*, 1988, 9, 289-311.

Lachin JM. Properties of simple randomization in clinical trials. *Controlled Clinical Trials*, 1988, 9, 312-326.

Matts JP and Lachin JM. Properties of permuted-block randomization in clinical trials. *Controlled Clinical Trials*, 1988, 9, 327-344.

Wei LJ and Lachin JM. Properties of the Urn randomization in clinical trials. *Controlled Clinical Trials*, 1988, 9, 345-364.

Lachin JM, Matts JP and Wei LJ. Randomization in clinical trials: Conclusions and recommendations. *Controlled Clinical Trials*, 1988, 9, 365-374.

Lachin JM and Wei LJ. Estimators and tests in the analysis of nonindependent 2 x 2 tables with partially missing observations. *Biometrics*, 1988, 44, 513-528.

Thall PF and Lachin JM. Analysis of recurrent events: Nonparametric methods for random interval count data. *Journal of the American Statistical Association*, 1988, 83, 339-347.

Halperin M, Gilbert PR and Lachin JM. Distribution-free confidence intervals for $Pr(X_1 < X_2)$. *Biometrics*, 1987, 43, 71-80.

Lachin JM and Foulkes MA. Evaluation of sample size and power for analyses of survival with allowance for non-uniform patient entry, losses to follow-up, non-compliance and stratification. *Biometrics*, 1986, 42, 507-519.

Thall PF and Lachin JM. Assessment of stratum-covariate interactions in Cox's proportional hazards regression model. *Statistics in Medicine*, 1986, 5, 73-83.

Wei LJ and Lachin JM. Two-sample asymptotically distribution-free tests for incomplete multivariate observations. *Journal of the American Statistical Association*, 1984, 79, 653-661.

Lachin JM. Sequential clinical trials for normal variates using interval composite hypotheses. *Biometrics*, 1981, 37, 87-101.

Lachin JM. Introduction to sample size determination and power analysis for clinical trials. *Controlled Clinical Trials*, 1981, 2, 93-113.

Lachin JM. Perceptions of the Coordinating Center: Foreword. *Controlled Clinical Trials*, 1980, 1, 125-126.

Lachin JM. Informed consent in clinical investigations. *Biometrics*, 1977, 33, 761-762.

Lachin JM. Sample size determinations for r x c comparative trials. *Biometrics*, 1977, 33, 315-324.

Lachin JM and Schachter J. On stepwise discriminant analyses applied to physiologic data. *Psychophysiology*, 1974, 11, 703-709.

Lachin JM. On a stepwise procedure for two population Bayes decision rules using discrete variables. *Biometrics*, 1973, 29, 551-564.

Medical: Glycemia Reduction Approaches for Diabetes Effectiveness: A Comparative Effectiveness Study (GRADE) (13 papers)

Tozzo V, Nathan DM, Krause-Steinrauf H, Lachin JM, Larkin ME, Mow C, Butera N, Cohen RM, Higgins JM; GRADE Research Group. Differences Between Glycemia Estimates from Hemoglobin A1c and Continuous Glucose Monitoring and Their Association with Complete Blood Counts. Diabetes Technol Ther. 2026 Feb 26: PMCID: PMC12970290.

Kahn SE, Tripputi M, Lachin JM, Balasubramanyam A, Banerji MA, Barzilay J, Cohen RM, Garvey WT, Gramzinski MR, Rasouli N, Rhee M, Seegmiller JC, Singh V, Sivitz WI, Steffes MW, Utzschneider K, DeFronzo RA; GRADE Research Group*. Differential Longitudinal Effects of Glucose-Lowering Medications on Glucagon and C-peptide Responses in the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE). Diabetes Care. 2026 Feb 1;49(2):325-334. PMCID: PMC12824799.

Seaquist ER, Phillips LS, Ghosh A, Baker C, Bergenstal RM, Crandall JP, Goland RS, Gramzinski MR, Hox SH, Hsia DS, Johnson ML, Lachin JM, Raskin P, Valencia WM, Waltje AH, Younes N; GRADE Research Group. Glycemia reduction in type 2 diabetes-Hypoglycemia outcomes: A randomized clinical trial. PLoS One. 2024 Nov 15;19(11):e0309907. PMID: 39546502; PMCID: PMC11567630.

Nathan DM, Herman WH, Larkin ME, Krause-Steinrauf H, Abou Assi H, Ahmann AJ, Brown-Friday J, Hsia DS, Harindhanavudhi T, Johnson M, Arends VL, Butera NM, Rosin SP, Lachin JM, Younes N; GRADE Study Research Group. Relationship Between Average Glucose Levels and HbA1c Differs Across Racial Groups: A Substudy of the GRADE Randomized Trial. Diabetes Care. 2024 Dec 1;47(12):2155-2163. doi: 10.2337/dc24-1362. PMID: 39312277; PMCID: PMC11655407.

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Lachin JM, Bebu I, Gao X, Nathan DM, Zinman B. Response to Comment on Lachin et al. Association of Estimated Time-in-Range Capillary Glucose Levels Versus HbA 1c With Progression of Microvascular Complications in the Diabetes Control and Complications Trial. Diabetes Care 2022; 45: 2445–2448. Diabetes Care. 2023 Jan 1;46(1).

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The GRADE Study Research Group. Glycemia Reduction in Type 2 Diabetes — Microvascular and Cardiovascular Outcomes. N Engl J Med. Sept 22, 2022; 387(12):1075-1088; doi: https://10.1056/NEJMoa2200436.

Nathan DM, Krause-Steinrauf H, Braffett BH, Arends VL, Younes N, McGee P, Lund C, Johnson M, Lorenzi G, Gao X, Steffes MW, Lachin JM, the GRADE Research Group, and the DCCT/EDIC Research Group. Comparison of central laboratory HbA1c measurements obtained from a capillary collection versus a standard venous whole blood collection in the GRADE and EDIC studies. PLOSOne. 2021 Nov 15; 16(11); doi: 10.1371/journal.pone.0257154 ;

Utzschneider KM, Younes N, Rasouli N, Barzilay JI, Banerji MA, Cohen RM, Gonzalez EV, Ismail-Beigi F, Mather KJ, Raskin P, Wexler DJ. Shape of the OGTT glucose response curve: relationship with β-cell function and differences by sex, race, and BMI in adults with early type 2 diabetes treated with metformin. *BMJ Open Diabetes Research and Care*. 2021 Sep 1;9(1):e002264

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Medical: Captopril Treatment of Diabetic Nephropathy (10 papers)

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Medical: National Cooperative Gallstone Study (NCGS) (19 papers)

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Miscellaneous Medical (52 papers)

Empa-Reg Outcome Study (12 papers of 52)

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Tygstrup N, Lachin JM, Juhl E. (editors). *The Randomized Clinical Trial and Therapeutic Decisions.* Marcel-Dekker, 1982. (ISBN: 0-8247-1856-9; 296 pages)

Lectures from the *First Advanced Course in Gastroenterology*. Dr. Lachin's chapters are entitled:

Statistical elements of the randomized clinical trial; pp. 77-102.
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The execution of a protocol; pp. 219-234.

e) Letters

See Section 7.b above

f) Book Reviews

None

g) Peer Reviewed Reports

None

h) Non-Peer Reviewed Reports

None

i) Abstracts (Last Three Years)

None

8) **Scholarly Presentations at Scientific Meetings** (**122)**. Others, e.g. seminars, are not shown.

Invited (86). All National or International

Lachin JM. Applications of the Wei-Lachin multivariate one-directional test to multiple outcomes. *International Conference on Recent Advances in Statistical Methodology With Applications in Clinical and Official Statistics*. Jan. 3-5, 2018 Kerala, India.

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Lachin JM. A multivariate one-directional test of multiple event-time outcomes. *Joint Statistical Meetings. American Statistical Association.* Chicago. August 1-4, 2016.

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Lachin JM. The Design and Baseline Data from the EMPA-REG Outcome Study. *European Association for the Study of Diabetes*. Stockholm, Sweden, 9, September 14-18, 2015

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Lachin JM. Statistical practice and challenges in chronic disease clinical trials – Diabetes and Cardiovascular Diseases. *Pharmaceutical and Regulatory Sciences Workshop: Revitalizing Clinical Trial Methodology and Translational Statistics.* Department of Biostatistics, Harvard School of Public Health. May 23-24, 2013.

Lachin JM. DCCT/EDIC Research Group Update. *Annual Rachmiel Levine Diabetes and Obesity Symposium.* City of Hope (Duarte, CA). March 13-16, 2013.

Lachin JM. What should the clinician know about statistics in clinical trials*? International Diabetes Federation.* December 5-8, 2011.

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Lachin JM. Comparative Effectiveness Research: Randomized Trials Versus Epidemiologic Evidence and the Role of Registries. *Second Annual Robert F. Woolson Lecture,* Department of Biostatistics, College of Public Health, University of Iowa. March 28, 2011.

Lachin JM. Levels of evidence from diabetes registries. *European Best Information through Regional Outcomes in Diabetes, International Diabetes Federation Science Taskforce.* January 23-25, 2011. Brussels, Belgium.

Lachin JM. Why good trials go bad. *Clinical Trials in Acute Kidney Injury: Current Opportunities and Barriers,* National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, December 2-3, 2010.

Lachin JM. Insulin glargine and cancer: Facts and Fallacies. *American Diabetes Association*. June 26-30, 2010, Orlando, Florida

Lachin JM. Intensive glycemic control and mortality in ACCORD. *American Diabetes Association*. June 26-30, 2010, Orlando, Florida

Lachin JM. Design considerations for outcome studies in type 1 diabetes. Juvenile Diabetes Research Foundation International, *Symposium on Prevention Trials for Complications of Type 1 Diabetes*, April 15-16, 2010, Crystal City, Virginia.

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Lachin, JM. Biostatistical Methods: The Assessment of Relative Risks. *Annual Deming Conference on Applied Statistics and Management*, Newark NJ, 2000.

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Lachin JM. Evaluation of the association of blood glucose levels with the risk of diabetes complications and hypoglycemia in the Diabetes Control and Complications Trial. *Joint Statistical Meetings, the American Statistical Association*, Baltimore, 1999.

Lachin JM. Ruminations on being an academic biostatistician. *Biostatistics in the Future*. Department of Biostatistics, University of Pittsburgh, 1999.

Lachin JM. Risk of microvascular complications of type 1 diabetes mellitus as a function of glycemic exposure (hba1c) in the diabetes control and complications

trial. National Institutes of Health Workshop: *Research Needs for the Design and Analysis of Surrogate Endpoints in Clinical Trials*, Potomac, MD, 1998.

Lachin JM. Design and interim monitoring of clinical trials. *Drug Information Association: Models for Launching and Coordinating Multi-Center Trials*. New Orleans, 1988.

Lachin JM. Discussion to "The Role of DSMBs and the Accumulating Evidence in the Conduct of Clinical Trials". *International Biometric Society, Eastern North American Region*, 1998.

Lachin JM. Role of data and safety monitoring boards in phase 3 clinical trials. *Drug Information Association: Clinical Trials and Drug Development in Biotechnology*, Dana Point, CA, 1998.

Lachin JM. Statistical considerations in the intention-to-treat principle. *Biopharmaceutical Applied Statistics Symposium*. Hilton Head, South Carolina, 1997.

Lachin JM. Is there a glycemic threshold in type 1 diabetes mellitus for development of microvascular complications: the Diabetes Control and Complications Trial (DCCT) perspective. *American Diabetes Association*, 1997.

Lachin JM. Trial design and other considerations. *American Diabetes Association Research Symposium on Prevention of Type I Diabetes in the General Population*. Estes Park, Colorado, 1996.

Lachin JM. Selection, definition, and measurement of outcomes. *American Diabetes Association Satellite Symposium on "Clinical Trials: Understanding Design, Management and Analysis - A Workshop for Researchers in Diabetes"*. San Francisco, 1996.

Lachin JM. Analysis strategies and issues. *American Diabetes Association Satellite Symposium on "Clinical Trials: Understanding Design, Management, and Analysis - A Workshop for Researchers in Diabetes"*. San Francisco, 1996.

Lachin JM. Experience and perspectives of the monitoring committee in NIH and industry sponsored trials. *Harvard University Shering-Plough workshop on "Flexible Strategies for Clinical Trials"*. Boston, May 30-31, 1996.

Lachin JM. The role of a central statistical center in multi-center collaborative studies: the role of the George Washington University Biostatistics Center in the Diabetes Control and Complications Trial (DCCT). *Department of Epidemiology and Biostatistics of the School of Health Sciences and Nursing of the University of Tokyo*, Japan, 1995.

Lachin JM. The effects of intensive vs. conventional treatment and exposure to hyperglycemic (HbA1c) on the risk of retinopathy progression in the Diabetes Control and Complications Trial (DCCT). *The Tokyo Society of Medical Sciences and the Faculty of Medicine at the University of Tokyo, and the Japanese Diabetes Society*, 1995.

Lachin JM. Distribution-free marginal analyses of repeated measures. *Drug Information Association's Second Annual Biostatistics Meeting in Tokyo*, 1995.

Lachin JM. Exposure to hyperglycemia and risk of complications in insulin dependent diabetes mellitus: time-dependent covariate analyses in the DCCT.

John C. Forbes Graduate Student Honors Colloquium. Medical College of Virginia, 1995. Distinguished guest lecturer.

Lachin JM. Some considerations in monitoring pharmaceutical trials. *International Biometric Society, Eastern North American Region*, 1995.

The DCCT Study Group (J. Lachin presenting). Glycemic exposure and the risk of progression of complications in the DCCT. *American Diabetes Association*, 1994.

Lachin JM. A review of methods for sample size evaluation based on power and precision. *Symposium on Sample Size Methodology*, Temple University, 1991.

Lachin JM. A review of some distribution-free methods for analysis of repeated measures from two populations. Conference on *Moving Clinical Trials Into the Twenty-first Century*, the Delaware Chapter of the American Statistical Association, 1991.

Lachin JM. Sample size Evaluation. Workshop organized for the *International Clinical Epidemiology Network*, Ninth Annual Meeting, Mombassa, Kenya, 1991.

Lachin JM. Sample size, precision and power. Paper presented to the *International Clinical Epidemiology Network*, Ninth Annual Meeting, Mombassa, Kenya, January 21-25, 1991.

Lachin JM. Randomization in clinical trials: Some statistical considerations. *Associates of Clinical Pharmacology*, 1988.

Lachin JM. The statistical properties of clinical indices for diabetic neuropathy. *American Diabetes Association Conference on Peripheral Neuropathy in Diabetes*, 1988.

Lachin JM. Study size and trial duration. (Pre-conference course: Some considerations in clinical trial design and analysis.) *Society for Clinical Trials*, 1987.

Lachin JM. Statistical considerations in the design of clinical trials in peripheral neuropathy. *Peripheral Neuropathy Association of America*, 1986.

Lachin JM. Simple randomization in clinical trials. *Society for Clinical Trials*, 1986. (In workshop organized by J. Lachin: The role of randomization in clinical trials).

Lachin JM. Randomization in clinical trials. *Delaware Chapter of the American Statistical Association*, 1986.

Lachin JM and Wright EC. Statistical considerations in the design and analysis of clinical trials of causal therapy in cirrhosis of the liver. *Fifth Advanced Course in Gastroenterology*, San Miniato, Italy, 1985.

Lachin JM. Design and analysis of an intervention trial to assess the effects of control of blood glucose on early vascular complications. *Biostatistics Symposium*, Diabetes Research Center, University of Washington, September 12, 1985.

Lachin JM. The design and analysis of clinical trials: Perspectives on recent developments. *Fortieth Annual Conference on Applied Statistics*, 1984.

Lachin JM. Ursodeoxycholic acid treatment of gallstones--International results. Symposium: *Update on treatment of gallstones: Role of ursodeoxycholic acid*, Nov. 29 - Dec. 2, 1984.

Lachin JM. Historically and randomized controlled clinical trials in nephritis. *International Congress of Nephrology*, 1984.

Lachin JM. Design of clinical trials in peripheral neuropathy. *Peripheral Neuropathy Association of America*, 1984.

Lachin JM. External monitoring of data coordinating center performance: Assessment of the biostatistical monitoring team in the National Cooperative Gallstone Study. *Society for Clinical Trials*, 1984.

Lachin JM. Design of clinical trials in apheresis. *International Society for Artificial Organs*, 1984.

Lachin JM. Statistical aspects of clinical trials of the effects of insulin pump therapy on microvascular disease. *Conference on Insulin Pump Therapy in Diabetes: Multi-Center Study of Effect on Microvascular Disease.* The Kroc Foundation, Santa Ynez Valley, California, March 21-25, 1983.

Lachin JM. Utilization of results from quality control programs: measurement of gallstone number and volume from cholecystograms. *Society for Clinical Trials*, 1981.

Lachin JM. Utilization of results from quality control programs: evaluation of morphological changes from liver biopsies. *Society for Clinical Trials*, 1981.

Anderson D and Lachin JM. Statistical reports in the National Cooperative Gallstone Study. Sixth *Annual Symposium on Coordinating Clinical Trials*, 1979.

Lachin JM. Some criteria for evaluating information systems in mental health. *Southern Regional Conference on Mental Health Statistics*, 1973.

Contributed (36). All National or International

Bebu I and Lachin JM. Longitudinal models with an interval censored binary covariate. *Population-based Time-to-event Analyses International Conference.* London University School of Hygiene and Tropical Medicine. London, 2016.

Lachin JM and Younes N. Phase II to Phase III Designs. Symposium on *Statistical Innovations in Clinical Trials, Statistical Methods in Biopharmacy, Societe Francaise de Statistique*, Paris, 2005.

Bautista OM and Lachin JM. Preserving alpha and power when over-ruling a group sequential boundary. *Society for Clinical Trials*, Toronto, 2000.

Lachin JM, Genuth S, Nathan DM, Davis MD, Cleary P and The EDIC Research Group. Prolonged Effects of DCCT Intensive Therapy on Complications After Four Years Of EDIC Follow-up. *American Diabetes Association*, San Diego, 1999.

Lachin JM, Cleary P, Davis MD, Molitch M, Nathan DM and The EDIC Research Group. Progression of retinopathy in the DCCT cohort after 4 years of follow-up in the Epidemiology of Diabetes Interventions And Complications (EDIC) study. *European Association for the Study of Diabetes*. Barcelona, 1998.

Lachin JM, Cleary P, Molitch M, Nathan DM and the DCCT Research Group. Pregnancy increases the risk of complications in the DCCT. *American Diabetes Association*, Chicago, 1998.

Lachin JM, Genuth S, Cleary P, Spielman R and the Diabetes Control and Complications Trial (DCCT) Research Group. Familial clustering of insulin dependent diabetes mellitus (IDDM) complications in the Diabetes Control and Complications Trial (DCCT). *Sixteenth International Diabetes Federation Congress*, Helsinki, 1997.

Lachin JM, Lorenz R, Cleary P, Nathan D and the DCCT Research Group. Risk factors for hypoglycemia in the Diabetes Control and Complications Trial (DCCT). *International Diabetes Epidemiology Group*, satellite meeting to the Sixteenth International Diabetes Federation Congress, Savonlinna, Finland, 1997.

Lachin JM. Poisson regression direct adjustment comparison of lifetables. Joint meeting of the *Society for Clinical Trials and International Society for Clinical Biostatistics*, Boston, 1997.

Lachin JM. Group sequential monitoring of distribution-free analyses of repeated measures. *International Biometric Conference*, Hamilton, New Zealand, 1992.

Lachin JM. Some useful distribution-free multivariate estimators and tests for the analysis of repeated measures in a clinical trial. *International Society for Clinical Biostatistics and the Society for Clinical Trials*, Brussels, Belgium, 1991.

Bain RP, Lachin JM, Keen H, Viberti GC. Designing longitudinal studies in progressive renal disease. *Society for Clinical Trials*, 1989.

Lachin JM and Wei LJ. Methods for the analysis of multiple nonindependent 2 x 2 tables with partially missing observations. *International Biometric Conference*, 1988.

Lachin JM, Lan SP and the Lupus Nephritis Collaborative Study Group. Termination of a clinical trial with no treatment group difference: the Lupus Nephritis Collaborative Study. Controlled Clinical Trials, 1987, 8, 280 (abstract). *Society for Clinical Trials*, 1987.

Thall PF and Lachin JM. Analysis of recurrent events based on random interval count data. Controlled Clinical Trials, 1986, 7, 237 (abstract). *Society for Clinical Trials*, 1986.

Foulkes MA and Lachin JM. Sample size and survival for survival time studies with non-uniform entry, losses to follow-up, non-compliance and stratification. Controlled Clinical Trials, 1985, 6, 230 (abstract). *Society for Clinical Trials*, 1985.

Thall PF and Lachin JM. Assessment of stratum-covariate interactions in Cox's proportional hazards regression model. *Society for Clinical Trials*, 1983.

Wei LJ and Lachin JM. Two sample distribution-free tests for censored multivariate observations, Biometrics, 1983, 39, 813 (abstract). *International Biometric Society (ENAR)*, 1983.

Schwartz SJ, Lan SP, Soloway RD, and Lachin JM, et al. Predicting dissolution in patients treated with chenodiol. *Gastroenterology*, 1982, 82, 1173 (abstract). *American Gastroenterology Association*, 1982.

Thistle JL, Cleary PA, Lachin JM, Tyor MP, Hersh T, et al. The natural history of untreated choleliathiasis in the National Cooperative Gallstone Study. Gastroenterology, 1982, 82, 197 (abstract). *American Gastroenterology Association*, 1982.

Grundy SM, Lan SP, Lachin JM, et al. Biliary lipid determinants of gallstone dissolution among patients in the National Cooperative Gallstone Study. Gastroenterology, 1982, 82, 1073 (abstract). *American Gastroenterology Association*, 1982.

Schoenfield LJ, Lachin JM et al. The National Cooperative Gallstone Study: A controlled trial of the efficacy and safety of chenodeoxycholic acid for dissolution of gallstones. Gastroenterology, 1981, 80, (abstract). *American Gastroenterology Association*, 1981.

Fisher RL, Anderson D, Boyer JL, Ishak K, Klatskin G, Lachin JM, Phillips MJ, et al. National Cooperative Gallstone Study: A prospective morphologic evaluation of hepatic toxicity of chenodeoxycholic acid (CDCA) in patients with cholelithiasis. Gastroenterology, 1981, 80, 1332 (abstract). *American Gastroenterology Association*, 1981.

Fisher RL, Anderson D, Boyer JL, Ishak K, Klatskin G, Lachin JM, Phillips MJ, et al. National Cooperative Gallstone Study: Abnormal hepatic morphology in patients with cholelithiasis--light (LM) and electron (EM) microscopic interpretation. Gastroenterology, 1981, 80, 1332 (abstract). *American Gastroenterology Association*, 1981.

Lachin JM and Rogers JS. Managing laboratory data in multicenter trials. *Fifth Annual Symposium on Coordinating Clinical Trials*, 1978.

Shaw LW, Ellenberg SS, Lachin JM, and Schlesselman SE. Constraints employed in randomization procedures. *Fifth Annual Symposium on Coordinating Clinical Trials*, 1978.

Lachin JM and Wong E. Data entry using the Datapoint 1100. *Fifth Annual Symposium on Coordinating Clinical Trials*, 1978.

Schachter J, Lachin JM and Wimberly FC. Newborn heart rate: relation to race and socioeconomic status. *American Psychosomatic Society*, 1976.

Lachin JM. Bayes extensions of some F and Chi-square tests, Biometrics, 1975, 31, 1005 (abstract). I*nternational Biometric Society (ENAR)*, 1975.

Schachter J, Patey J, Wimberly F, and Lachin JM. Maternal weight gain and newborn blood pressure level. Psychophysiology, 1975, 12, (abstract). *Society for Psychophysiological Research*, 1974.

Schachter J, Kerr J, Wimberly F and Lachin JM. Racial differences in newborn heart rate level. Psychophysiology, 1974, 11, (abstract). *Society for Psychophysiologic Research*, 1973.

Lachin JM. Two population discriminant functions under prior logical constraints. *Statistics Section, Virginia Academy of Sciences*, 1973.

Lachin JM and Schachter J. On the interpretation of stepwise discriminant function analyses applied to evoked physiologic data. Psychophysiology, 1973, 10, 199 (abstract). *Society for Psychophysiological Research*, 1972.

Schachter J, Kerr J, Lachin JM, Khachaturian Z, Williams T, and Faer M. Heart rate reactivity of newborn offspring of schizophrenic parents. *Psychophysiology*, 1972, 9, 273 (abstract). *Society for Psychophysiological Research*, 1971.

Williams TA, Lachin JM, and Schachter J. The multiphasic heart rate response to auditory clicks in neonates: Sources of variance in response to repetitive stimuli. *Psychophysiology*, 1971, 8, 277 (abstract). *Society for Psychophysiological Research*, 1970.

Khachaturian Z, Kruger R, Schachter J, Williams T, and Lachin JM. A comparison of two methods of analyzing cardiac activity; R-R interval vs. heart rate. *Psychophysiology*, 1970, 6, 647-648 (abstract). *Society for Psychophysiological Research*, 1969.

9) **University Service** (Specify names and dates)

a) Committee service: Department, School, Senate, University

2016-7. Member, Search Committee, Professor and Director of the Biostatistics Center. Department of Epidemiology and Biostatistics, Milken Institute School of Public Health.
2013, Member, Oscar and Shoshana Trachtenberg Prize for Scholarship selection committee.
2012, member, review committee for GWU Research Facilitating Funds for the Medical Center.
1998-9. Member, Search Committee, Professor and Director of the Biostatistics Center Medical Center Unit. Department of Epidemiology and Biostatistics.
1995-1999, Chair, Executive Committee. The Biostatistics Center Medical Center Unit. GWU Medical Center
1996-8, member, search committee, Professor and Chair, Department of Epidemiology and Biostatistics, School of Public Health and Health Services.
1997-8, member, Task Force on an Associate Vice President for Research, GWU Medical Center
1997-8, member, search committee, Associate Vice President for Research, GWU Medical Center.
1996-7, Chair, search committee, Associate to Full Professor of Statistics
1995-6, Chair, search committee, Associate to Full Research Professor of Statistics, to direct the Biostatistics Center Medical Center Unit.
1993-6, member, Advisory Council on Research, Office of the Associate Vice-President for Academic Affairs and Research.
1993-5, member, Department of Economics Self-study Evaluation Review Committee.
1993-5, Chair, Committee for the establishment of graduate programs in biostatistics and epidemiology.
1993-4, member, Special Review Committee, by appointment to the Vice President for Academic Affairs.
1986-7, member, Committee on Sponsored Research
1986-7, member, Middle States Subcommittee on Academic Computing.

1986-7, member, Junior Scholar Incentive Program Committee
1986-7, member, Committee on Scholarly and Creative Awards.

b) Administrative assignments: Department, School, University
1980-1985 Assistant Director, The Biostatistics Center, GWU
1985-1988 Co-Director, The Biostatistics Center, GWU
1988-2000 Director, The Biostatistics Center, GWU
2001-2010 Co-Director, The Biostatistics Center, GWU
2010-2012 Interim Director, The Biostatistics Center, GWU.
1995 – 2004 Program Director for Biostatistics and Chair of the Executive Committee for the graduate degree program in Biostatistics and Epidemiology, jointly administered by the Department of Epidemiology and Biostatistics and the Department of Statistics.

c) Mentoring to a member of the faculty. None
d) Service to admissions, alumni, or student groups. None
e) Community service (other than public health practice activities listed below). None

10) **Professional Society Membership and Leadership**

a) **Societies**
American Statistical Association
Biometric Society
1989-91, Liaison Officer to the American Statistical Association.
Institute of Mathematical Statistics
Royal Statistical Society
International Statistical Institute
International Chinese Statistical Association
Society for Clinical Trials
Committee on Fellows (Chair, 2011-12, member 2007-8)
President (2002-3)
Board of Directors, member, 1982 - 1986.
Finance Committee, chairman, 1981 - 1984.
Program Committee, member, 1978, 79, 80, 95.
Workshop Sessions, chairman, 1979, 80.
Organizer and lecturer, Pre-Conference Short Course, "Some Considerations in Clinical Trial Design and Analysis", 1987.
Organizer and speaker, Workshop on "The Role of Randomization in Clinical Trials", 1986.
Meeting host and chairman of session on "Organization and Management of Coordinating Centers," 1978.
Controlled Clinical Trials. Editorial Board, 1986-1989.
Society for Epidemiologic Research
International Society for Clinical Biostatistics

American Diabetes Association (Professional Section, Council on Epidemiology and Statistics)
2010-2013, Member, Editorial Board, *Diabetes,*
American Diabetes Association Consensus Development Conference: *C-Peptide as an Endpoint in Type 1 Diabetes Intervention Trials.* Chicago, October 21-2, 2001.
American Diabetes Association Workgroup: *Implications of the United Kingdom Prospective Diabetes Study*, 1998.
European Association for the Study of Diabetes
International Diabetes Epidemiology Group
International Diabetes Federation
2010-2014, Member, Science Task Force
Drug Information Association

b) **Symposia and Conferences (Partial List) as Participant** *(Presentations listed separately in Section 8 above)*

International Conference on Recent Advances in Statistical Methodology With Applications in Clinical and Official Statistics. Jan. 3-5, Kerala, India

10th Annual Conference on Statistical Issues in Clinical Trials. University of Pennsylvania, Philadelphia. April 19, 2017.

World Congress on Clinical Trials in Diabetes. Berlin, Germany. Nov. 30 – Dec. 1, 2016.

Sixth Annual International Symposium on the Evaluation of Clinical Trials (Methodologies and Applications). Renmin University, Bejing, China. July 11-12, 2015.

Data Monitoring Committee Think Tank. Duke Clinical Research Institute, Tyson's Corner, VA. June 4-5, 2015.

Cardiovascular Disease and Type 1 Diabetes. National Institutes of Health. October 8-9 2014.

Pharmaceutical and Regulatory Sciences Workshop: Revitalizing Clinical Trial Methodology and Translational Statistics. Department of Biostatistics, Harvard School of Public Health. May 23-24, 2013.

Annual Rachmiel Levine Diabetes and Obesity Symposium. City of Hope (Duarte, CA). March 13-16, 2013.

Retinal Vessels as Biomarkers; Seeing the Development of Diabetes Complications. National Institutes of Health. October 3-4, 2011.

Clinical Trials in Acute Kidney Injury: Current Opportunities and Barriers, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, December 2-3, 2010.

Symposium on Prevention Trials for Complications of Type 1 Diabetes, Juvenile Diabetes Research Foundation International, April 15-16, 2010, Crystal City, Virginia.

Workshop on the Handling of Missing Data in Clinical Trials. September 9, 2009. Institute of Medicine, National Academy of Sciences, Washington DC.

Regulatory Review of Drugs for Type 2 Diabetes and Cardiovascular Risk: Beyond HgbA1c. June 13-15, 2007. Duke Clinical Research Institute, Washington DC.

European Diabetes Expert Forum: The Cambridge Symposium, Cambridge University, UK, 2007.

First Swiss Update on Key Clinical Trials in Diabetes and Metabolic Disorders. Bern, Switzerland, February, 2006

Issues in Data Monitoring Committees. January 16-18, 2003. Duke Clinical Research Institute, Washington DC.

Metabolic Imprinting and the Long-term Complications of Diabetes Mellitus: Bench to Bedside and Back. April 10-11, 2003. National Institutes of Health, Bethesda MD.

Perspectives on the Biostatistical Sciences: A Symposium in Memory of Samuel W. Greenhouse. June 11, 2001, National Institutes of Health. Chair, Organizing Committee; member, Program Committee.

NIH Consensus Conference: Diet and Exercise in Noninsulin Dependent Diabetes Mellitus. December 8-10, 1986. Member, Consensus Panel.

NIH Centennial Initiative: Kidney Disease of Diabetes Mellitus. November 3-4, 1986. Member, Committee on Clinical Research.

Fifth Advanced Course in Gastroenterology, the Italian Society for Gastroenterology: Cirrhosis of the Liver, Methods and Fields of Research. San Miniato, Italy, October 28 - November 2, 1985. Invited speaker (see publication #40).

Eighth International Bile Acids Meeting: Recent Advances in Bile Acids Research. Cortina D'Ampezzo, Italy, March 22-24, 1984.

Conference on Changing Concepts in Bioavailability and Clinical Trials. University of Maryland School of Pharmacy, Baltimore, October 1982. Moderator, Session on Quality Assurance: Concepts and Procedures for Clinical Trials.

International Conference on Hepatotoxicity Due to Drugs and Chemicals. John E. Fogarty International Center for Advanced Study in the Health Sciences, NIH, Bethesda, Maryland, November 14-16, 1977. (See Publication #16.)

First Advanced Course in Gastroenterology, The Italian Society for Gastroenterology: The randomized Controlled Trial. Villa Monastero, Varenna, Italy, September 28 - October 2, 1975. (See books below.)

11) **Editorial Peer Review Activities** (grant review activities, journals, etc.)
Numerous reviews of grant applications and journal article submissions.

12) **External Activities/Partnerships** (List all external professional activities including consultancies, the name of the company, government agency, organization, private or public foundation or other entity involved, your relationship to it, and dates of service. Also list all visiting professorships).

Numerous past consultancies to government agencies, and the private sector including service on pharmaceutical Scientific Advisory Boards, Steering Committees and Data and Safety Monitoring Boards. All activities conducted on my own time and not as an employee of GWU. See 14.a below.

No Visiting Professorship.

13) **Teaching/Learning Portfolio** (Include dates of participation for all categories.)

a) **Educational Program Leadership**

1993-1995, Chair, Committee for the Establishment of a PhD Program in Biostatistics and in Epidemiology.

1995-2004, Chair, Executive Committee, Graduate Program in Biostatistics and Epidemiology; and Program Director for Biostatistics.

b) **Courses Taught**

Department of Statistics

Introduction to Biostatistics (Statistics 1127), lecturer

Data Analysis (Statistics 6210), developer and lecturer

Design of Medical Studies (formerly Statistics 224, now PH 6247), developer and lecturer;

Biostatistical Methods (formerly Statistics 225, now PH 6266), lecturer

Advanced Biostatistical Methods (formerly Statistics 226), lecturer

Survival Analysis (Statistics 6227), developer and lecturer.

Department of Epidemiology and Biostatistics

Biostatistical Methods (PH 6266), developer and lecturer

c) **Students and Trainees: Advising/Mentoring**

Undergraduate (number by year)

None

Master's (number by year)

None

Capstone advisor (name, degree program, year)

None

Doctoral dissertation/primary thesis advisor (name, degree program, year)

Milton Fan, Ph.D. Statistics, 1986, *Estimation of Parameters for the Logistic Regression Model with Partial Incomplete Observations.*.

Yuko Palesch, Ph.D. Statistics, 1990, *R-Sample(R>2) Multivariate Rank Tests and Related Estimators of Population Differences.*

Naji Younes, Ph.D. Statistics, 1994, *A Family of Event-Time Models with Smooth Baseline Hazards*.

Oliver Bautista, Ph.D. Statistics, 1996, (Co-Advisor with K.K. Gordon Lan), *Analysis of Overdispersed Poisson Count Data.*.

Mingxiu Hu, Ph.D. Statistics, 1997, *Robust Estimating Functions with Nuisance Parameters.*.

Theodore Diaz, Ph.D. Statistics, 1999, (Co-Advisor; Advisor: Robert Smythe). *Simultaneous Testing and Estimation of Trend in Proportion Using Historical Controls.*

Yvonne Sparling, Ph.D. Biostatistics, 2002, *Parametric Survival Models for Interval-Censored Data with Time-Dependent Covariates*.

Pablo Bonangelino, Ph.D. Biostatistics, 2003, (Co-Advisor with Thomas Louis). *Maximum Efficiency Robust Tests for the Focused Clustering of Disease.*

Ainong Zhou, Ph.D. Biostatistics, 2006, (Co-Advisor with Giovanni Parmigiani), *Bayes Factors Comparing Two Multi-Normal Covariance Matrices and Their Application to Microarray Data Analysis*

Mark VanRaden, Ph.D. Biostatistics, 2007, *Cumulative Logit - Poisson and Cumulative Logit - Negative Binomial Compound Regression Models for Count Data*

Ruthanna Davi, PhD Biostatistics, 2008, *Methods to Jointly Evaluate Sensitivity, Specificity, and Kappa in Diagnostic Imaging Studies.*

Yong Ma, PhD Biostatistics, 2010 (Co-advisor with Yinglei Lai), *Flexible Isotonic Regression in Survival Data Analysis*

Marinella Temprosa, PhD Biostatistics, 2012, *An Imputation-Estimation Algorithm Using Time-Varying Auxiliary Covariates for a Longitudinal Model When Outcome is Missing by Design*.

Wanjie Sun, PhD Biostatistics, 2012 (Co-advisor with Michael Larsen), *Models for a Longitudinal Quantitative Outcome with Multivariate Normal (MVN) Distribution Censored by Therapeutic Intervention.*

Barbara Braffett, PhD Epidemiology, 2013, *The Effects of Smoking on Metabolic Control and Diabetes-Related Complications in Type 1 Diabetes.*

Gregory Sandoval, PhD Biostatistics, 2021 (Co-advisor with Ionut Bebu). *A Cost-Efficient Design for Clinical Trials*

Doctoral dissertation/research committee (name, degree program, year)
Numerous, not recorded

Doctoral preliminary oral examination (name, degree program, year)
Numerous, not recorded

Doctoral thesis reader/final oral examination (name, degree program, year)
Numerous, not recorded

Postdoctoral fellows mentored
None

Supervision of students in internships, practicum experience, mentored research.
None

14) **Public Health Practice Portfolio**

a) Participation on Advisory Panels (all paid)

Scientific Advisory Board (member). Tolerion Inc. Development of pharmaceuticals for induction of immune tolerance in auto-immune diseases. 2015 - 2019

Steering Committee (member). EMPA-REG Outcomes Study, Boehringer-Ingelheim, 2010 - 2017

Data and Safety Monitoring Board (member). Time to Reduce Mortality in End-Stage Renal Disease (TiME) Trial. National Institute of Diabetes, Digestive and Kidney Diseases, 2013 - 2016

Steering Committee (member). Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS), Duke Clinical Research Institute, University of Oxford Diabetes Trials Unit, Merck, 2009 - 2017.

Data and Safety Monitoring Board (member). Apnea Positive Pressure Long-term Efficacy Study (APPLES). National Heart, Lung and Blood Institute, 2003 - 2010.

Data and Safety Monitoring Board (Vice-chair). Look AHEAD: Action for Health in Diabetes. National Institute of Diabetes, Digestive and Kidney Diseases, 2001-2012

Steering Committee (member). A Diabetes Outcomes Progression Trial (ADOPT), Glaxo SmithKline, 2000 - 2010.

Data and Safety Monitoring Committee (member). Aspirin and Folate Prevention of Large Bowel Polyps. National Cancer Institute, 1997 - 2004.

Data Safety and Quality Monitoring Group (member). Diabetes Prevention Trial - Type I. National Institute of Diabetes, Digestive and Kidney Diseases, 1994 - 2001.

Data and Safety Monitoring Committee (member), Studies of Vesnarinone in Congestive Heart Failure. Otsuka Pharmaceuticals Co., 1987 - 1994.

Treatment Effects Monitoring Advisory Committee (chairman), Glaucoma Laser Trial, National Eye Institute, Coordinating Center - Johns Hopkins University, 1983 - 1995.

Policy-Advisory Board (member), Hypertension Prevention Trial, National Heart, Lung and Blood Institute, Coordinating Center - Johns Hopkins University, 1982-1986.

Operations Committee (member), Veterans Administration Cooperative Study Protocol No. 213, "Treatment of Mild Hypertension in the Aged. Anti-Hypertensive Effectiveness and Patients' Toleration of Different Regimens," 1981-1986.

Patient Safety Monitoring Committee (member), National Cooperative Dialysis Study, National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases, Coordinating Center - Harvard University School of Public Health, 1979-1981.

Gastrointestinal Drugs Advisory Committee (member), Food and Drug Administration, 1978-1982; consultant, 1983 - 1984.

Services Research and Epidemiologic Studies Review Committee (member), National Institute of Mental Health, 1977-1980.

Consultant to various review committees of the NIH and the FDA.

Member of Data, Safety Monitoring Boards for various studies in industry.

b) Program or Project Development

None

c) Consultations

Many, no record retained.

d) Testimony

Many, no record retained.

e) Clinical Practice Activities
Not applicable

f) Governmental (e.g., IPA) Assignments
None.