Curriculum Vitae

Fall 2007

Janis Patricia Hardwick

EECS Department
College of Engineering
University of Michigan
Ann Arbor, MI 48109

Correspondence Via:
928-284-2742
jphard@umich.edu
www.eecs.umich.edu/˜jphard

Education

1978 B.A. (Mathematics), University of California, Santa Barbara

1979 M.A. (Mathematics), University of California, Santa Cruz

1984 M.S. (Biostatistics), University of California, Los Angeles

1986 Ph.D. (Biostatistics), University of California, Los Angeles

Thesis Title: *The Modified Bandit: An approach to ethical allocation in clinical trials.*
Supervised by T. S. Ferguson.

Recent Employment, Academic Positions

Visiting Associate Research Scientist, EECS Department, University of Michigan, 2000– .

Visiting Scientist/Consultant, Research Statistics Unit, GlaxoSmithKline, Collegeville, PA, 2002–2004.

Visiting Associate Professor/Scholar, Department of Statistics, Purdue University 1997-1999.

Assistant Professor, Department of Statistics, University of Michigan, 1989–1997

Visiting Assistant Professor, Department of Statistics, University of Michigan, 1987–1989.

Postdoctoral Researcher, Department of Biomathematics, UCLA, 1986–1987.

Research Statistician/Lecturer, BMDP Statistical Software, Los Angeles, California, 1984–1987.

Honors

National Science Foundation *Presidential Young Investigator,* 1991–1996.

Research Grants

Principal or Co-Principal Investigator:

- National Science Foundation: *Computationally Aggressive Approaches to Adaptive Allocation,* 2000–2004. Co-Principal Investigator with Q.F. Stout. ($247,000)
- National Science Foundation: *Computationally Aggressive Approaches to Sequential Design,* 1995–2000. Co-Principal Investigator with Q.F. Stout. ($80,000)
- Research Experiences for Undergraduates supplement to National Science Foundation DMS-9157715, 1995–1999. ($7,500)
- National Science Foundation: CISE Postdoctoral Research Associateship, 1995–1997. *This grant provided support for a postdoc to work on computer intensive approaches to sequential design problems.* ($46,200)
- National Science Foundation DMS-9157715: *Presidential Young Investigator Award,* 1991–1996. ($275,000 plus $150,000 matching funds provided by Kendall Square Research.)
- National Institute of Health and University of Michigan Biomedical Research Support Grant #1271: *Applications of Supercomputer Technology to Problems in Medical Statistics,* 1989–1992. ($50,000)
- National Science Foundation DMS-8914238: *Research in Sequential Design, Optimal Stopping and Survival Analysis,* 1989–1992. ($67,000)
- National Science Foundation DMS-8413452: *Estimation in Large Samples.* Postdoctoral Associate, 1987–1989. (These were independently generated funds that could be attached to a senior investigator's grant of my choice.) ($24,000)

Others

- National Institute of Mental Health NIMH-37188: *Statistical Software for Mental Health Research.* Postdoctoral Associate, 1986–1987.
- National Science Foundation *Scientific Computing Research Equipment for the Mathematical Sciences* DMS-8904476: Co-investigator, 1989. (I initiated this grant and did a majority of the work on it.)
- National Science Foundation *Research Experiences for Undergraduates* awarded to University of Michigan Mathematics Department, 1991–1994.
- National Science Foundation *Scientific Computing Research Equipment for the Mathematical Sciences* DMS-9104613: Co-investigator, 1991. (I also initiated this grant.)
- National Science Foundation: *Acquisition of Massively Parallel Processor for Scientific Computing Applications and Computer Science Engineering,* Senior investigator, 1992–1995.

Refereed Publications

1. Response adaptive designs that incorporate switching costs and constraints, (with Q. F. Stout) (2007). *J. of Statistical Planning and Inference* **137:** 2654-2665.

2. Parallel programs for adaptive designs, (with Q. F. Stout) (2006). *Handbook on Parallel Computing and Statistics*, ed. E.J. Kontoghiorghes, Marcel Dekker, pp. 347–373.

3. New adaptive designs for delayed response models, (with Q.F. Stout and R. Oehmke) (2006). J. Statistical Planning and Inference. **136:** 1940–1955.

4. Optimal screening designs with flexible cost and constraint structures, (with Q. F. Stout) (2005). *J. of Statistical Planning and Inference* **132:** 149-162.

5. Directed walks for dose response problems with competing failure modes, (with M. Meyer and Q.F. Stout) (2003). *Biometrics* **59:** 229-236.

6. Optimal adaptive designs for delayed response models: exponential case, (with R. Oehmke and Q. F. Stout) (2001) *MODA6: Advances in Model-Oriented Design and Analysis*, (A. Atkinson, P. Hackl, W. Mller, ed's), Physica Verlag, Heidelberg, pp. 127–134.

7. Optimizing a unimodal response function for binary variables, (with Q. F. Stout) (2001). *Optimum Design 2000*, (A. Atkinson, B. Bogacka, and A. Zhigljavsky, eds.), Kluwer, 2001, pp. 195-208.

8. Optimal few stage allocation rules, (with Q. F. Stout) (2001). *Journal of Statistical Planning and Inference* **104:** 121–145.

9. Scalable algorithms for adaptive statistical designs, (with R. Oehmke and Q. F. Stout) (2001). *Scientific Programming* **8** 183-193.

10. Using path induction for evaluating sequential allocation procedures (with Q. F. Stout) (1999) *SIAM Journal of Scientific Computing* **21:** 67–87.

11. A program for sequential allocation of three Bernoulli populations, (with R. Oehmke and Q. F. Stout) (1999). *Computational Statistics and Data Analysis* **31:** 397-416.

12. Sequentially deciding between two experiments for estimating a common success probability, (with C. Page and Q. F. Stout) (1998). *Journal of American Statistical Association.* **93:** 1502–1511.

13. Flexible algorithms for creating and analyzing adaptive designs (1998) (with Q. F. Stout) *New Developments and Applications in Experimental Design: Institute of Mathematical Statistics Lecture Notes* **34:** 91–105. (B. Rosenberger, W. Wong & N. Flournoy, ed.'s).

14. Asymptotic expansions for randomly censored survival data, (1996). *Statistics and Probability Letters* **26:** 187–197.

15. Optimal allocation for estimating the mean of a bivariate polynomial, (with Q. F. Stout) (1996). *Sequential Analysis* **15:** 71–90.

16. A modified bandit as an approach to ethical allocation in clinical trials, (1995). *Adaptive Designs: Institute of Mathematical Statistics Lecture Notes* **25:** 223–237. (B. Rosenberger & N. Flournoy, ed.'s).

17. Exact computational analyses for sequential allocation problems, (with Q. F. Stout) (1995). *Adaptive Designs: Institute of Mathematical Statistics Lecture Notes* **25:** 65–87. (B. Rosenberger & N. Flournoy, ed.'s).

18. Using historical controls in clinical trials: Application to ECMO, (with Donald Berry) (1994). *Fifth Purdue International Symposium on Statistical Decision Theory and Related Topics.* **V:** 141–156. (S. Gupta & J. Berger, ed.'s)

19. Maximizing the duration of owning a relatively best object, (with T. Ferguson and M. Tamaki) (1991). *Contemporary Mathematics: Strategies for Sequential Search and Selection in Real Time,* American Mathematics Association **125:** 37–58. (T. Ferguson & S. Samuels, ed.'s).

20. Sequential allocation for an estimation problem with ethical cost, (with M. Woodroofe). (1990) *Annals of Statistics* **18:** 1358–1367.

21. Computational problems associated with minimizing the risk in a simple clinical trial, (1989). *Contemporary Mathematics: Statistical Multiple Integration.* American Mathematics Association **115:** 239–257. (N. Flournoy & R. Tsutakawa, ed.'s).

22. Recent progress in clinical trial designs that adapt for ethical purposes, (1989). (Discussion) *Statistical Science,* **4:** 327–336.

23. Stopping rules for proofreading, (with T. Ferguson) (1989). *Journal of Applied Probability* **26:** 304–313.

Under Revision or Submitted

24. Response adaptive designs for balancing complex objectives. (with Q. F. Stout) Submitted 2006.

Conference Proceedings

25. New adaptive designs that incorporate switching concerns, (with Q. F. Stout) (2005). *Fifth St. Petersburg Workshop on Simulation* pp. 305–312. (S.M. Ermakov, Yu.N. Kashtanov, and V.B. Melas, eds.), NII Chemistry, St. Petersburg.

26. Optimal screening designs with flexible cost structures, (with Q. F. Stout) (2001) 4^{th} *St. Petersburg Workshop on Simulation* pp. 253-260, (S.M. Ermakov, Yu.N. Kashtanov, and V.B. Melas, eds.), NII Chemistry, St. Petersburg.

27. Minimizing the costs of screening trials, (with Q.F. Stout) (1999). *Computing Science and Statistics* **31:** 440–444.

28. Adaptive allocation in the presence of missing observations, (with R. Oehmke and Q. F. Stout) (1998). *Computing Science and Statistics* **30** 219–223.

29. Predicting algorithm performance, (with J. Landrum and Q. F. Stout) (1998). *Computing Science and Statistics* **30** 309–314.

30. A parallel program for 3-arm bandits, (with R. Oehmke and Q. F. Stout) (1997). *Computing Science and Statistics* **29** 390–395.

31. Sequential allocation with minimal switching, (with Q. F. Stout) (1996). *Computing Science and Statistics,* **28** 567–572.

32. Determining optimal few stage allocation rules, (with Q. F. Stout) (1995). *Computing Science and Statistics,* **27** 342–346.

33. Statistical analysis of communication times on the IBM SP2, (with T. Tabe and Q. F. Stout) (1995). *Computing Science and Statistics,* **27** 347–351.

34. Optimal adaptive equal allocation rules, (with Q. F. Stout) (1992). *Computing Science and Statistics,* **24:** 597–601.

35. Optimal allocation for estimating the product of two means, (with Q. F. Stout) (1992). *Computing Science and Statistics,* **24:** 592–596.

36. Bandit strategies for ethical sequential allocation, (with Q. F. Stout) (1991). *Computing Science and Statistics,* **23:** 421–424. Wiley, New York.

37. Supercomputer-intensive multivariable randomization tests, (with N. Schork) (1990). *Computing Science and Statistics,* **22:** 509–513. Wiley, New York.

38. Recent progress in repeated significance tests, (1989) *American Statistical Association: Proceedings of the Biopharmaceutical Section,* 9–15.

Additional Publications

39. *New Researchers' Survival Guide* (Co-edited and written with N. Altman, D. Banks and K. Roeder.) (1991) Institute of Mathematical Statistics, Hayward, CA.

40. Report of the New Researchers' Committee, (with NRC) (1991). *Statistical Science,* **6:** 163–174.

41. Rejoinder to Readers' Comments to the New Researchers' Committee Report, (with NRC) (1992). *Statistical Science,* **7:** 265–266.

42. Adaptive allocation in clinical trials: The ECMO controversy. University of Michigan, Statistics Department, Technical Report #185

43. 2R Regression Diagnostics (1986) *BMDP Statistical Software Newsletter* #19.

44. Diagnostic Plots in 2R (1987) *BMDP Statistical Software Newsletter* #20.

Invited Presentations at Conferences

- I.M.S. Central Regional Meeting, Dallas, Texas; March 22–25, 1987.
- NSF/CBMS Regional Conference: Group Invariance Applications in Statistics (M. L. Eaton, Principal Lecturer), University of Michigan, June 15–19, 1987. *Participant.*
- I.M.S. Western Regional Meeting, Honolulu, Hawaii; June 15–17, 1988.
- I.M.S. Annual Meeting, I.M.S. Probability Symposium, NSF Pathways to the Future Workshop, Fort Collins, Colorado; August 14–19, 1988.
- Joint Summer Research Conference on Statistical Multiple Integration, Arcata, California; June 18–22, 1989.
- Joint Statistical Meetings, Washington, D.C., August 14–17, 1989.
- I.M.S. & Biometric Society Western Regional Meetings; Bozeman, Montana; June 17–20, 1990.
- Joint Summer Research Conference on Sequential Search and Selection in Real Time; Amherst, Massachusetts; June 21–27, 1990.
- I.M.S. & Biometric Society Western Regional Meetings, Santa Barbara, CA; July 1–3, 1991.
- Statistical Stochastic Processes; Oberwolfach, Germany; November 30 – December 6, 1991.
- Joint Summer Research Conference on Adaptive Design, Mt. Holyoke, MA; July 18–25, 1992.
- European Statistician's Meeting, Bath, England; September 14–19, 1992.
- Joint Statistical Meetings; San Francisco, CA, August 8–12, 1993.
- 26^{th} Symposium on Interface: Computing Science and Statistics; Research Triangle Park, NC, June 15–18, 1994.
- New Directions in Sequential Analysis; Chapel Hill, NC, June 18–19, 1994.
- Joint I.M.S. and Statistical Society of Canada Meetings; Montreal, Canada, July 9–13, 1995.
- Joint Summer Research Conference on New Developments and Applications in Experimental Design, Seattle, WA, June 28–July 3, 1997.
- MODA5: 5^{th} International Workshop on Model-Oriented Data Analysis, Marseilles, France, June 22–26, 1998.

- Statistical Society of Canada National Meeting, Regina, Saskatchewan, Canada, June 6–9, 1999.
- Optimum Design 2000, Cardiff, Wales, April 12–14, 2000.
- X International Symposium on Applied Stochastic Models and Data Analysis, Compiègne, France, June 12-15, 2001.
- 4^{th} St. Petersburg Workshop on Simulation, St. Petersburg, Russia, June 18–23, 2001.
- MODA6: 6^{th} International Workshop on Model-Oriented Data Analysis, Puchberg, Austria, June 25–29, 2001.
- Statistics of Optimal Dosing, organized by Henry Stewart Conference Studies. Washington, D.C., July 25, 2001.
- International Biometric Society Annual Conference, Freiburg, Germany, July 21–26, 2002.
- GlaxoSmithKline Internal Conferences, Collegeville, PA. Seminars in September 2001 and April & May 2002.
- Design and Analysis of Experiments, Chicago, IL, May 14-17, 2003.
- 5^{th} St. Petersburg Workshop on Simulation, St. Petersburg, Russia, June 2005.
- MODA8: 8^{th} Advances in Model-Oriented Design and Analysis, Almagro, Spain, June 4-8, 2007.
- Adaptive Trial Design: Strategic Implementation and Management of Adaptive Trials, Philadelphia, PA, September 10-11, 2007.

Invited Seminars at Universities

University of California at Berkeley, Statistics Department.

University of California at Los Angeles, Departments of Mathematics; Biostatistics; & Biomath.

University of California at Santa Barbara, Stat & Applied Prob Program.

Carnegie Mellon University, Statistics Department, Pittsburgh, PA.

University of Chicago, Statistics Department, Chicago, IL.

Columbia University, Statistics Department, New York, NY.

University of Connecticut, Statistics Department, Storrs, CO.

University of Florida, Statistics Department, Gainesville, FL.

George Washington University, SCIS Department, Washington, DC.

University of Georgia, Statistics Department, Athens, GA.

Harvard University, Biostatistics Department, Cambridge, MA.

University of Michigan, Departments of Statistics; Biostatistics; & EECS , Ann Arbor, MI.

Michigan State University, Statistics Department, East Lansing, MI.

University of Minnesota, School of Statistics, Minneapolis/Saint Paul, MN.

University of North Carolina, Biostatistics Department, Chapel Hill, NC.

Ohio State University, Statistics Department, Columbus, OH.

University of Pennsylvania, Statistics Department, Philadelphia, PA.

University of Pittsburgh, Mathematics Department, Pittsburgh, PA.

Purdue University, Statistics Department, West Lafayette, IN.

University of Rochester, Statistics Department, Rochester, NY.

Rutgers University, Statistics Department, New Brunswick, NJ.

Temple University, Statistics Department, Philadelphia, PA.

University of Virginia, Statistics Department, Charlottesville, VA

Wayne State University, Mathematics Department, Detroit. MI.

Pharmaceutical Interests

As a visiting scientist with the Research Statistics Unit at GSK, I sought exposure to a variety of pharmaceutical issues. Much of this exposure came via seminars, web education programs and discussions with researchers outside the Unit. Within the unit, there were continual discussions of problems presented to us by project statisticians. However, my primary research focus and outputs were as follows:

- Written review of literature on integrated phase I/phase II trial designs. Designs for hybrid studies of this nature are still in their infancy and this is an ongoing area of research for me.
- Broad review of literature relating to dose finding for First in Man (FIM) studies. This project was motivated by the 2002 draft FDA guidelines for FIM trials. This is an active research area that ranges from simplistic allometric methodologies to complex pk models, and those based on compound descriptors and genetic indicators.

Some other directly relevant pharmaceutical experience includes:

- Nearly all my research has focused on the design of clinical trials (see papers).
- I've done legal consulting on compound patents as well as more classical pharmaceutical consulting on clinical trial design and analysis.
- I have been an invited presenter at a number of professional workshops on adaptive designs intended for members of the pharmaceutical industry.