

BIOGRAPHICAL SKETCH

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| NAME David A. Schoenfeld | POSITION TITLE Professor of Medicine and Biostatistics |
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EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.*)

| INSTITUTION AND LOCATION | DEGREE (if applicable) | YEAR(s) | FIELD OF STUDY |
|------------------------------------|---------------------------|---------|------------------------|
| Reed College, Portland, Oregon | BA | 1967 | Mathematics |
| Univ. of Oregon, Portland, Oregon | MA | 1968 | Mathematics |
| Univ. of Oregon, Portland, Oregon | PhD | 1974 | Mathematics-Statistics |
| Stanford University Medical School | Post doc. | 1975 | Biostatistics |

A. Positions and Honors.**Positions and Employment**

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| 1975-1977 | Research Assistant Professor, State University of New York at Buffalo |
| 1977-1981 | Assistant Scientist, Dana-Farber Cancer Institute, Boston, MA |
| 1977-1981 | Assistant Professor, Department of Biostatistics, Harvard School of Public Health |
| 1981-1986 | Associate Professor of Biostatistics, Dana-Farber Cancer Institute, Boston, MA |
| 1981-1998 | Associate Professor in the Department of Biostatistics, Harvard School of Public Health |
| 1984- | Associate Biostatistician, Massachusetts General Hospital, Boston, MA |
| 1985-1998 | Associate Professor of Biostatistics in the Department of Medicine, Harvard Medical School |
| 1985- | Director of the Massachusetts General Hospital Biostatistics Center |
| 1998- | Professor of Medicine, Harvard Medical School, Boston MA |
| 1999- | Professor, Department of Biostatistics, Harvard School of Public Health, Boston, MA |

Honors

Member ISI (1991), Fellow ASA (1992)

B. Selected peer-reviewed publications (in chronological order).

- Schoenfeld DA**, Gelber R. Designing and analyzing clinical trials which allow institutions to randomize patients to a subset of the treatments under study. *Biometrics*, 1979; 35:825-830.
- Schoenfeld DA**. Determining the number of patient necessary to test a combination of treatments. *Can Clin Trials*, 1979; 2:155-156.
- Schoenfeld DA**. Chi-squared goodness of fit tests for the proportional hazards regression model. *Biometrika*, 1980; 67:145-153.
- Schoenfeld DA**. Statistical considerations for pilot studies. *Int Rad Oncol, Biol & Phys*, 1980; 6:371-374.
- Schoenfeld DA** and Kallman R. Determining the labeling index in autoradiography. *Cell & Tiss Kin*, 1980; 13:339-347.
- Schoenfeld DA**. Test based on linear combinations of the orthogonal components of the Cramer-von Mises statistic when parameters are estimated. *Ann Stat*, 1980; 8:1017-1022.
- Schoenfeld DA**. The asymptotic properties of nonparametric tests for comparing survival distributions. *Biometrika*, 1981; 68:316-319.
- Schoenfeld DA** and Richter J. Nomograms for calculating the number of patients needed for a clinical trial with survival as an endpoint. *Biometrics*, 1982; 38:163-170.
- Schoenfeld DA**. Residuals for the proportional hazards regression model. *Biometrika*, 1982; 69(1):239-241.
- Schoenfeld DA**. Sample Size Formulae for the Proportional Hazards Regression Model. *Biometrics*, 1983;39:499-503
- Lagakos SW and **Schoenfeld DA**. Consequences of misfit for covariate models of censored survival data. *Biometrics*, 1984; 40:1037-48.
- Schoenfeld DA**. Confidence intervals for normal means under order restriction, with applications to toxicology experiments and low dose extrapolation. *JASA*, 1986; 81:186-195.
- Schoenfeld DA** and Tsiatis AA. A modified logrank test for highly stratified data. *Biometrika*, 1987; 74:167-175.
- Finkelstein DM and **Schoenfeld DA**. Analysis of multiple tumor data from a rodent Carcinogenicity experiment. *Biometrics*, 1989; 45(1):219-230.

15. Byar DP, **Schoenfeld DA**, Green SB, Amato DA, Anderson JR, Collins R, Davis R, DeGruttola V, Ellenberg SS, Finkelstein DM, Freedman LS, Gail M, Gatsonis C, Gelber RD, Lagakos S, Lefkopoulou M, Peto J, Peto R, Peto T, Simon R, Tsiatis AA, and Zelen M. Design considerations for AIDS trials. *NEJM*, 1990; 323:1343-1348.
16. Finkelstein DM, Moore DF, **Schoenfeld DA**. A proportional Hazards Model for truncated AIDS data. *Biometrics*, 1993; 49(3):731-740.
17. Finkelstein DM, Schoenfeld DA. Analyzing survival in the presence of an auxiliary variable. *Statistics in Medicine*. 1994; 13:1747-1754.
18. Katznelson L, Finkelstein JS, **Schoenfeld DA**, Rosenthal DI, Anderson EJ, Kilbanski A. Increase in bone density and lean body mass during testosterone administration in men with acquired hypogonadism. *J Clin Endocrinol & Metab*, 1996; 8(12):4358-65.
19. Cudkovic ME, McKenna-Yasek D, Sapp PE, Chin W, Geller B, Hayden DL, **Schoenfeld DA**, Hosler BA, Horvitz Hr, Brown RH. Epidemiology of mutations in superoxide dismutase in amyotrophic lateral sclerosis. *Annals of Neurology*, 1997; 41(2):210-21.
20. Finkelstein DM, **Schoenfeld DA**, Stamenovic E. Analysis of multiple failure time data from an AIDS clinical trial. *Stat in Med*, 1997; 16:951-961.
21. Ma L, Penforinis A, Wang X, **Schoenfeld DA**, Tuomilehto-Wolf E, Metcalfe K, Hitman G, Faustman D. Evaluation of TAP1 polymorphisms with insulin dependent diabetes mellitus in Finish diabetic patients. The Childhood Diabetes in Finland (DiMe) Study Group. *Human Immunology*, 1997; 53:159-66.
22. **Schoenfeld DA**, Thorpe WP, Sheridan RL, Cassem EH, Tompkins RG. Objective estimates of the probability of death from burn injuries. *NEJM*, 1998; 338:362-366.
23. Finkelstein DM and **Schoenfeld DA**. Combining mortality and longitudinal measures in clinical trials. *Stat in Med*, 1999; 18(11):1341-54.
24. Betensky R and **Schoenfeld DA**. Nonparametric estimation in a cure model with random cure times. *Biometrics*, 2000; 57:282-286.
25. Greenberg SM, Tennis MK, Brown LB, Gomez-Isla T, Hayden DL, **Schoenfeld DA**, Walsh KL, Corwing C, Daffner KR, Friedman P, Meadows ME, Sperling RA, Growdon JH. Donepezil therapy in clinical practice: a randomized crossover study. *Archives of Neurology*, 2000; 57:94-9.
26. Sheridan RL, Hinson MI, Liang MH, Nackel AF, **Schoenfeld DA**, Ryan CM, Mulligan JL, Tompkins RG. Long-term outcome of children surviving massive burns. *JAMA*, 2000; 283:69-73.
27. The ARDS Network. Ventilation with lower tidal volumes as compared with traditional tidal volumes for Acute Lung Injury and the Acute Respiratory Distress Syndrome. *NEJM*, 2000; 342:1301-8.
28. The ARDS Network. Ketoconazole for early treatment of acute lung injury and acute respiratory distress syndrome: A randomized controlled trial. *JAMA*, 2000; 283:69-73.
29. Smith MR, McGovern FJ, Fallon MA, Schoenfeld D, Kantoff PW, Finkelstein JS. Low Bone Mineral Density in Hormone-Naïve Men with Prostate Carcinoma. *Cancer*, 2001; 91:2238 – 45
30. Ling TL, **Schoenfeld DA**, Xiaoling W, Penforinis A, Faustman D. Bayesian analysis of case control polygenic etiology studies with missing data. *Biostatistics*, 2001; 2(3):309-322.
31. **Schoenfeld DA**. A simple algorithm for designing group sequential clinical trials. *Biometrics*, 2001; 57:972-974.
32. Shefner JM, Brown RH Jr, Cole D, Chaturvedi P, **Schoenfeld D**, Pastuszak K, Matthews R, Upton-Rice M, Cudkovic ME. Effect of neurophilin ligands on motor units in mice with SOD1 ALS mutations. *Neurology*, 2001; 57(10):1857-61.
33. Smith MR, Finkelstein JS, McGovern FJ, Zietman AL, Fallon MA, **Schoenfeld DA**, Kantoff PW. Changes in body composition during androgen deprivation therapy for prostate cancer. *J Clinical Endocrinology & Metabolism*, 2002; 87(2):599-603.
34. Eisner MD, Thompson BT, **Schoenfeld DA**, Anzueto A, Matthay MA. The ARDS Network. Airway pressures and early barotraumas in patients with acute lung injury and acute respiratory distress syndrome. *Amer J Respiratory & Critical Care Med*, 2002; 165(7):978-82.
35. **Schoenfeld DA**, Bernard GR. ARDS Network. Statistical evaluation of ventilator-free days as an efficacy measure in clinical trials of treatments for acute respiratory distress syndrome. *Critical Care Med*, 2002; 30(8):1772-7.
36. Finkelstein DM, Goggins WB, **Schoenfeld DA**. Analysis of failure time data with dependent interval censoring. *Biometrics*, 2002; 58(2):298-304.
37. Leder BZ, LeBlanc KM, **Schoenfeld DA**, Eastell R, Finkelstein JS. Differential effects of androgens and estrogens on bone turnover in normal men. *J Clin Endocrinol Metab*, 2003; 72:115-127.

C. Research Support

Ongoing Research Support

5P01HL18646-25 - Cosimi (PI) 04/01/76-2/29/04
NIH/NHLBI
Tolerance, An Approach to Cardiac Allo and Xenotransplants

The major goals of this project are to improve the outcome following organ transplantation by defining the essential conditions for and clarifying the mechanisms involved in donor specific tolerance induction.

Role: Core B Statistician

N01-HR-46064 - Schoenfeld (PI) 9/30/94-6/30/04
NIH / NHLBI
Clinical Coordinating Center for a Clinical Network for the Treatment of Adult Respiratory Diseases Syndrome

The major goals of this project are the coordination, design, and statistical analysis of clinical trials in ARDS.

Role: PI

5P01 AG12992-07 - Brown (PI) 4/15/95-8/31/05
NIH
Oxidative and Excitatory Toxicity in Neurodegeneration

The major goal is to provide statistical support for clinical and laboratory studies.

Role: Statistical Consultant

2R01 CA74302-05 - Finkelstein (PI) 7/15/97-6/30/04
NIH/NCI
Statistical Methods for Research in Cancer and AIDS

The major goals of this project are developing statistical methods for analyzing cancer and AIDS studies.

Role: Co-Investigator

5 P30 DK40561-08 - Walker (PI) 9/30/99-8/31/04
NIH/NIDDK
Harvard Clinical Nutrition Research Center

The major goals of the project are the support of clinical trials and laboratory studies involving nutrition.

Role: Biostatistician

1R01NS39988-02 - Cudkowicz (PI) 7/29/00-6/30/03
NINDS Clinical Trial Grant
Clinical Trial of Topiramate in ALS

This proposal is to test the experimental agent Topiramate in subjects with ALS.

Role: Statistical Consultant

IU54 GM62119-01AI - Tompkins (PI) 9/1/01-8/31/06
NIH/NIGMS
Inflammation of the Host Response to Injury

The major goal of this project is to provide statistical support for clinical studies.

Role: Head of Biostatistics Core

FD-R-1981-01 - Klibanski (PI) 9/30/01-9/29/04
NIH
TheraDerm Administration in Women with Hypopituitarism (IND No. 60,962)

The major goal of this project is to provide statistical support for clinical studies.
Role: Statistical Consultant

Completed Research Support

5R01 GM55326-03 - Schoenfeld (PI) 8/1/97-7/31/00
NIH / NIGMS
Statistical Methods for Genetic Case Control Studies

5M01 RR01066-25 - Nathan (PI) 12/1/97-2/28/02
NIH/NCRR
General Clinical Research Center

The major goals of this project are the conduct of clinical studies
Role: Head of Biostatistics Core

The major goals of the project are to develop statistical methods for case control studies.
Role: PI

1K24 MH 02025-01 - Goff (PI) 7/1/01 – 6/30/06
NIH
New Treatments in Mechanisms in Schizophrenia

The major goal of this project is to provide statistical support for the clinical trials in schizophrenia.
Role: Statistical Consultant