

BIOGRAPHICAL SKETCH

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NAME David A. Schoenfeld, Ph.D.		POSITION TITLE Director of MGH Biostatistics Center, MGH	
eRA COMMONS USER NAME DSCHOENFELD		Professor of Medicine, Harvard Medical School	
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, Eugene, Oregon	MA	1968	Mathematics
Univ. of Oregon, Eugene, Oregon	PhD	1974	Mathematics-Statistics
Stanford University Medical School	Post doc.	1975	Biostatistics

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

- 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
 1984-2004 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/Appointments

- 1991 Elected Member of International Statistical Institute
 1992 Fellow of the American Statistical Association
 2004 Elected Member of Food and Drug Administration Pulmonary-Allergy Advisory Committee

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; 35:825-30.
- Schoenfeld DA. Chi-squared goodness of fit tests for the proportional hazards regression model. *Biometrika*. 1980; 67:145-53.
- Schoenfeld DA. Statistical considerations for pilot studies. *Int J Radiat Oncol Biol Phys*. 1980; 6:371-4.
- Schoenfeld DA. The asymptotic properties of nonparametric tests for comparing survival distributions. *Biometrika*. 1981; 68:316-9.
- Schoenfeld DA, Richter J. Nomograms for calculating the number of patients needed for a clinical trial with survival as an endpoint. *Biometrics*. 1982; 38:163-70.
- Schoenfeld DA. Residuals for the proportional hazards regression model. *Biometrika*. 1982; 69(1):239-41.
- Schoenfeld DA. Sample size formulae for the proportional hazards regression model. *Biometrics*. 1983; 39:499-503
- Lagakos SW, 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; 81:186-95.
- Schoenfeld DA, Tsiatis AA. A modified logrank test for highly stratified data. *Biometrika*. 1987; 74:167-75.
- 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. *N Engl J Med.* 1990; 323:1343-8.
12. Finkelstein DM, Moore DF, Schoenfeld DA. A proportional hazards model for truncated AIDS data. *Biometrics.* 1993; 49(3):731-40.
 13. Finkelstein DM, Schoenfeld DA. Analyzing survival in the presence of an auxiliary variable. *Stat Med.* 1994; 13:1747-54.
 14. 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.
 15. Finkelstein DM, Schoenfeld DA, Stamenovic E. Analysis of multiple failure time data from an AIDS clinical trial. *Stat Med.* 1997; 16:951-61.
 16. Greenberg SM, Tennis MK, Brown LB, Gomez-Isla T, Hayden DL, Schoenfeld DA, Walsh KL, Corwing C, Daffner KR, Friedmanz P, Meadows ME, Sperling RA, Growdon JH. Donepezil therapy in clinical practice: a randomized crossover study. *Arch Neurol.* 2000; 57:94-9.
 17. The ARDS Network. Ventilation with lower tidal volumes as compared with traditional tidal volumes for acute lung injury and the acute respiratory distress syndrome. *N Engl J Med.* 2000; 342:1301-8.
 18. 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.
 19. Matthew R. Smith, Francis J. McGovern, Mary Anne Fallon, David Schoenfeld, Phillip W. Kantoff, Joel S. Finkelstein. Low bone mineral density in hormone-naïve men with prostate carcinoma. *Cancer.* 2001; 91: 2238-45.
 20. Ling TL, Schoenfeld DA, Xiaoling W, Penfornis A, Faustman D. Bayesian analysis of case control polygenic etiology studies with missing data. *Biostatistics.* 2001; 2,3:309-22.
 21. Schoenfeld DA. A simple algorithm for designing group sequential clinical trials. *Biometrics.* 2001; 57:972-4.
 22. Shefner JM, Brown RH Jr, Cole D, Chaturvedi P, Schoenfeld D, Pastuszak K, Matthews R, Upton-Rice M, Cudkowicz ME. Effect of neurophilin ligands on motor units in mice with SOD1 ALS mutations. *Neurology.* 2001; 57(10):1857-61.
 23. 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 Clin Endocrinol Metab.* 2002; 87(2):599-603.
 24. 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. *Am J Respir Crit Care Med.* 2002; 165(7):978-82.
 25. 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. *Crit Care Med.* 2002; 30(8):1772-7.
 26. Finkelstein DM, Goggins WB, Schoenfeld DA. Analysis of failure time data with dependent interval censoring. *Biometrics.* 2002; 58(2):298-304.
 27. Fava M, Evins A.E, Dorer D.J, Schoenfeld D.A. The problem of the placebo response in clinical trials of psychiatric disorders: culprits, possible remedies, and a novel study design approach. *Psychother Psychosom.* 2003; 72:115-27.
 28. Cudkowicz ME, Shefner JM, Schoenfeld DA, et al. A randomized, placebo-controlled trial of topiramate in amyotrophic lateral sclerosis. *Neurology.* 2003; 61(2 of 2):456-64.
 29. Finkelstein, DM, Muzikansky, A, Schoenfeld, DA, Comparing survival of a sample to that of a standard population. *J Natl Cancer Inst.* 2003; 95(19):1434-9.
 30. Brower RG, Morris A, MacIntyre N, Matthay MA, Hayden D, Thompson T, Clemmer T, Lanken PN, Schoenfeld D. ARDS Clinical Trials Network, National Heart, Lung, and Blood Institute, National Institutes of Health. Effects of recruitment maneuvers in patients with acute lung injury and acute respiratory distress syndrome ventilated with high positive end-expiratory pressure. *Crit Care Med.* 2003; 31(11):2592-7.
 31. Brower RG, Lanken PN, MacIntyre N, Matthay M, Ancukiewicz M, Schoenfeld D, Thompson BT, National Heart, Lung, and Blood Institute ARDS Clinical Trials Network. Higher versus lower positive end-expiratory pressures in patients with the acute respiratory distress syndrome. *N Engl J Med.* 2004; 351:327-26.

C. Research Support

Ongoing Research Support

N01-HR-46064 Schoenfeld (PI) 9/30/94-7/31/07
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

RFP HR-05-05 (Schoenfeld) 10/1/05 - 8/31/12
NIH / NHLBI

Clinical Coordination Center for a Clinical Research Network for the Treatment of Acute Lung Injury and Acute Respiratory Distress Syndrome
The major goals of this project are the coordination, design, and statistical analysis of clinical trials in ARDS.
Role: PI

2R01 CA74302-05 Finkelstein (PI) 7/15/97-6/30/07
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

IU54 GM62119-05 Tompkins (PI) 9/1/01-9/29/11
NIH/NIGMS

Inflammation of the Host Response to Injury
The major goal of this project is to provide statistical support for clinical studies.
Role: PI of Biostatistics Core

1R01 NS049640-02(Cudkowicz) 9/30/2004-8/31/2009
NIH-NINDS

Clinical Trial of Ceftriaxone in ALS
The major goal of this project is to provide statistical support for clinical studies.
Role: Statistical Consultant

BAA RM 04-23 (Schoenfeld Subcontract) 9/30/04-9/29/07
NIH

Re-Engineering Clinical Research in Critical Care
The major goal of this project is to conduct research using computerized bedside electronic protocols.

5M01 RR01066-25 Nathan (PI) 12/1/97-11/30/07
NIH/NCRR

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

2PO1 HL18646-26A1 Cosimi (PI) 9/30/03-8/31/08
NIH/NHLBI

Tolerance - An Approach To Cardiac Allo & Xenotransplants
Core B: (Cosimi)
Administration and Biostatistics

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 of induction.

Role: Core B Statistician

5-P30-DK40561-10 Walker (PI) 4/1/06-- 3/31/11

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: Head of Biostatistics Core

5 P50 AG05134-21 (Growdon) 4/1/04-3/31/09

NIH/NIA

Massachusetts Alzheimer's Disease Research Center

ADRC's Database Management & Statistics Core (aka Core C).

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

1U19 AI066705 (Madsen) 7/01/05 - 06/30/10

NIH/NIAID

Thoracic Allograft Tolerance in Non-Human Primates

The studies proposed in this PPG should yield clinically relevant information that will result in the development of new tolerance strategies applicable to heart and lung allografts recipients and lead to the development of better assays to monitor and predict patients that achieve tolerance and those at risk for the development of chronic graft loss.

R01 AT001638-02(Fava) 04/15/04-03/31/09

NCCAM

\$313,240

A Double-Blind, Placebo-Controlled Study of the Alternative Therapy S-adenosyl-L-methionine (SAME) vs. Escitalopram in Major Depressive Disorder (MDD)

The primary purpose of this study is to compare the efficacy and safety and tolerability of SAME or escitalopram with placebo for the treatment of Major Depressive Disorder.

Completed Research Support

FD-R-1981-01 Klibanski (PI) 9/30/01-12/31/04

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: Co-Investigator

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

1R01 NS041409-01A1 Greenberg (PI) 2/1/03-1/31/06

NIH

National Institute on Neurologic Diseases and Stroke

NC-758 for Prevention of Recurrent Cerebral Hemorrhage

The major goal of this project is to develop a multi-center phase II pilot study of the safety, tolerability and preliminary efficacy of NC-758 for secondary; prevention of recurrent CAA-related intracerebral hemorrhage.

Role: Statistical Consultant