

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

Stephen W. Lagakos		Professor	
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
Carnegie -Mellon University, Pittsburgh, PA	BS	1968	MATHEMATICS
George Washington University, Washington, DC	M.PH	1972	MATHEMATICAL STATISTICS
George Washington University, Washington, DC	PH.D.	1972	MATHEMATICAL STATISTICS

A. Positions and Honors.**Positions:**

- 1972-1973 **Visiting Assistant Professor**, Department of Statistics, State University of New York at Buffalo
 1973-1977 **Assistant Professor**, Statistical Science Division, State University of New York at Buffalo
 1978-1979 **Assistant Professor**, Department of Biostatistics, Harvard School of Public Health, and Division of Biostatistics & Epidemiology, Dana-Farber Cancer Institute, Boston, MA
 1979-1986 **Associate Professor**, Department of Biostatistics, Harvard School of Public Health, and Division of Biostatistics & Epidemiology, Dana-Farber Cancer Institute, Boston, MA
 1986- **Professor**, Department of Biostatistics, Harvard School of Public Health, Boston, MA
 1999-present Director, Center for Biostatistics in AIDS Research, Harvard School of Public Health, Boston, MA
 1999-present Henry Pickering Walcott Professor and **Chair**, Department of Biostatistics, Harvard School of Public Health, Boston, MA

Appointments: (Partial list)

- 1989-1996 Director, Statistical and Data Analysis Center, AIDS Clinical Trials Group
 1995- FDA, Senior Biomedical Research Service Credentials Committee
 1997- Editorial Board (Statistical Consultant), *New England Journal of Medicine*
 1997- NIAID HIV Vaccine Trials Data & Safety Monitoring Board
 1999- NIH AIDS Study Section
 2002- Associate Editor, Journal of the American Statistical Association
 2002- Chair-Elect, Section U (Statistics), American Association for the Advancement of Science

Honors:

- Pi Mu Epsilon (1971); Elected Fellow of International Statistical Institute (1980), Institute of Mathematical Statistics (1984), American Statistical Association (1988), American Association for Advancement of Science (1988), Institute of Medicine (2002); Spiegelman Gold Medal Award, American Public Health Association (1983) Howard M. Temin Award for Clinical Science (co-recipient, 1993); NIH Merit Award (2001);

B. Selected peer-reviewed publications (in chronological order). Do not include publications submitted or in preparation.**Bibliography:** (partial list)

- Lagakos SW**, Lim LL-Y, Robins J. Adjusting for early treatment termination in comparative clinical trials. *Stat in Med*, 1990; 9:1417-1424.
 Volberding PA, **Lagakos SW**, Koch M, et al. Safety and efficacy of Zidovudine in asymptomatic HIV infected individuals with less than 500 CD4+ cells/mm. *NE J Med*, 1990; 322:941-949.
 Richman D, Grimes J, **Lagakos S**. Effect of stage of disease and drug dose on Zidovudine susceptibilities of isolates of human immunodeficiency virus. *J AIDS*, 1990; 3:743-746.
 Dawson JD and Lagakos SW. Analyzing laboratory marker changes in AIDS clinical trials. *J of Acquired Immune Deficiency Syndromes*, 1991; 4:667-676.
Lagakos S, Fischl MA, Stein DS, Lim L, Volberding P. Effects of Zidovudine therapy in minority and other subpopulations with early Human Immunodeficiency Virus type 1 (HIV) infection. *J Am Med Assoc*, 1991; 266:2709-2712.
 Begg MD and **Lagakos SW**. Effects of mismodeling on tests of association based on logistic regression models. *Annals of Statistics*, 1992; 20:1929-1952.
Lagakos SW and Hoth DF. Surrogate markers in AIDS: Where are we? Where are we going? *Annals of Internal Medicine*, 1992; 116:599-601.

- Kahn JO, **Lagakos SW**, Richman DD, et al. A comparison of didanosine to Zidovudine in HIV-infected persons who have tolerated at least 16 weeks of zidovudine: A randomized controlled trial. *NE J Med*, 1992; 327:581-587.
- Kim MY, DeGruttola V, **Lagakos SW**. Analyzing doubly censored data with covariates, with application to AIDS. *Biometrics*, 1993; 49:13-22.
- Begg MD and **Lagakos SW**. Loss in efficiency caused by omitting covariates and misspecifying exposure in logistic regression models. *J Am Stat Assoc*, 1993; 88:166-170.
- Choi S, **Lagakos SW**, Schooley R, Volberding PA. CD4+ lymphocytes are an incomplete surrogate marker for clinical progression in persons with asymptomatic HIV infection. *Ann Int Med*, 1993; 118:674-680.
- Dawson JD and **Lagakos SW**. Size and power of two-sample tests of repeated measures. *Biometrics*, 1993; 49:1022-1032.
- Gomez G and **Lagakos SW**. Estimation of the infection time and latency distribution of AIDS with doubly censored data. *Biometrics*, 1994; 50:204-212.
- Kim M and **Lagakos SW**. Assessing drug compliance using longitudinal marker data, with application to AIDS. *Stat Med*, 1994; 13:2141-2153.
- Volberding PA, **Lagakos SW**, Grimes JM, et al. The duration of Zidovudine benefit in persons with asymptomatic HIV infection: Prolonged evaluation of ACTG 019 subjects. *J Amer Med Assoc*, 1994; 272:437-442.
- Volberding A, **Lagakos SW**, Grimes JM, et al. A comparison of immediate with deferred Zidovudine therapy for asymptomatic HIV-infected adults with CD4 cell counts of 500 or more per cubic millimeter. *NE J Med*, 1995; 333:401-407.
- Kim HM and **Lagakos SW**. Nonparametric inference of a failure time distribution when the failure times are estimated. *Stat in Med*, 1996; 15:2475-2490.
- Elashoff M and **Lagakos SW**. HIV treatment strategies utilizing virologic and immunologic markers as criteria for changing treatments. *Stat in Med*, 1996; 15:2425-2443.
- Li QH and **Lagakos SW**. Use of the Wei-Lin-Weissfeld method for the analysis of a recurring and a terminating event. *Stat in Med*, 1996; 16:925-9407.
- Hu XJ and **Lagakos SW**. Group sequential analyses for the mean function of a repeated measures process. *Stat in Med*, 1998; 18:2287-2299.
- Hu X J and **Lagakos SW**. Nonparametric interim analyses using repeated confidence bands. *Biometrika*, 1998; 86:517-529.
- Kahn J, **Lagakos SW**, et al. Efficacy and safety of Adefovir Dipivoxil with antiretroviral therapy. *J Amer Med Assoc*, 1999; 282:2305-2312.
- Dixon DO and **Lagakos SW**. Should data and safety monitoring boards share confidential interim data? *Controlled Clinical Trials*, 2000; 21:1-6, Discussion 54-5.
- Cheng DM and **Lagakos SW**. The one-sample problem from eradication studies of chronic viral infections. *Biometrics*, 2000; 56:626-33.
- Kahn JO, Cherng DW, Mayer K, Murray H, **Lagakos SW**. An evaluation of HIV-1 Immunogen, an immunologic modifier, administered to HIV-1 infected people with 300-549 CD4+ T cells: A randomized, controlled study with clinical endpoints. *J Am Med Assoc*, 2000; 284:2193-2202.
- Weinberg JM and **Lagakos SW**. Asymptotic behavior of linear permutation tests under general alternatives, with application to test selection and study design. *JASA*, 2000; 95:596-607.
- Weinberg JM and **Lagakos SW**. Linear rank tests under general alternatives, with application to summary statistics computed from repeated measures data. *J Stat Planning & Inference*, 2001; 96:109-127.
- Weinberg JM and **Lagakos SW**. Efficiency comparisons of rank and permutation tests based on summary statistics computed from repeated measures data. *Stat in Med*, 2001; 20:705-31.
- DiRienzo G and **Lagakos SW**. Bias correction for score tests arising from mis-specified proportional hazards regression models. *Biometrika*, 2001; 88: 421-434.
- Balasubramanian R and **Lagakos SW**. Estimation of the timing of perinatal transmission of HIV. *Biometrics*, 2001; 57:1048-1058
- DiRienzo G and **Lagakos SW**. Effects of model misspecification on tests of nor randomized treatment effect arising from Cox's proportional hazards model. *J Royal Statistical Soc Series B*, 2001; 63:745-757.
- Gulick RM, Hu XJ, Fiscus SA, Fletcher CV, Haubrich R, Cheng H, Acosta E, **Lagakos SW**, et al. Durability of response to treatment among antiretroviral-experienced subjects: 48-week results from AIDS Clinical Trials Group Protocol 359. *J Infect Dis*, 2002; 186:626-33.
- Balasubramanian R and **Lagakos SW**. Estimation of a failure time distribution based on imperfect diagnostic tests. *Biometrika*, 2003; 90:171-182.

Lagakos SW. Clinical trials and rare diseases. *N Engl J Med*, 2003; 348:2455-6.

C. Research Support. List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of principal investigator identified above.

LAGAKOS, S

ONGOING

R37 AI24643 Lagakos 4/1/87-1/31/06
NIH-NIAID (MERIT Award)
Statistical Methods in AIDS Research

Role: Principal Investigator

The major goals of this project are to develop statistical models and methods to analyze various types of AIDS data and better understand the natural history and future spread of the epidemic.

U01 AI38855 Hughes (PI) 1/1/96-12/31/04
NIH-NIAID
Adult ACTG-Statistical and Data Management Center

Role: Dr. Lagakos is involved with protocols and review of study design and analyses, and serves as a member of the Steering Committee.

The major goal of this project is to conduct studies on the treatment of patients with human immunodeficiency virus (HIV) and related diseases.