

# CURRICULUM VITAE

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1. **Date:** June 10, 2013

2. **Biographical Information**

Peter B. Gilbert, Ph.D.

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University of Washington, Department of Biostatistics

3. **Education**

- University of Washington, B.S., Mathematics (1992)
- University of Washington, M.S., Biostatistics (1994)
- University of Washington, Ph.D., Biostatistics (1996)
- Postdoctoral Training: Harvard School of Public Health, Department of Biostatistics (1997)

4. **Licensure:** Not Applicable

5. **Professional Positions**

- **Research Assistant**, Department of Mathematics, University of Washington (1991)
- **Graduate Research Assistant**, Coronary Artery Surgery Study, University of Washington (1992-1993)
- **Graduate Research Assistant**, HIVNET, University of Washington (1995-1996)
- **Research Fellow**, Department of Biostatistics, Harvard School of Public Health (1997)
- **Assistant Professor**, Department of Biostatistics, Harvard School of Public Health (1998-2001)
- **Assistant Member**, Fred Hutchinson Cancer Research Center (2001-2002)
- **Associate Member**, Fred Hutchinson Cancer Research Center (2002-2007)
- **Member**, Fred Hutchinson Cancer Research Center (2007-present)
- **Research Assistant Professor**, Department of Biostatistics, University of Washington School of Public Health (2002-2004)
- **Research Associate Professor**, Department of Biostatistics, University of Washington School of Public Health (2004-2008)
- **Research Professor**, Department of Biostatistics, University of Washington School of Public Health (2008-present)
- **Deputy Director of Statistical Sciences**, Statistical Center for HIV/AIDS Research and Prevention, Fred Hutchinson Cancer Research Center (2005-2006)
- **Co-Director, Statistical Data Management Center of the HIV Vaccine Trials Network**, Statistical Center for HIV/AIDS Research and Prevention, Fred Hutchinson Cancer Research Center (2004-2011)

- **Principal Investigator, Statistical Data Management Center of the HIV Vaccine Trials Network,** Statistical Center for HIV/AIDS Research and Prevention, Fred Hutchinson Cancer Research Center (2011-present)

## 6. Honors, Awards, Scholarships

- B.S, Magna Cum Laude (1992)
- Honorary Donovan J. Thompson Award for outstanding performance as a student in biostatistics, University of Washington (1994)
- School of Public Health and Community Medicine Outstanding Student Scholarship, University of Washington (1995)
- Senior Biostatistics Student Award, University of Washington (1996)
- Excellent Teaching Rating, each of two semester courses, Harvard School of Public Health (2000-2001)
- Ross L. Prentice Professorship at the Department of Biostatistics, University of Washington (2005-2006)
- MERIT Award (R37) from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, for the grant, “Statistical Methods in HIV Vaccine Efficacy Trials” (2010)

## 7. Professional Activities (outside FHRC and University of Washington)

- **Reviewer of Grants and Proposals**

Reviewer of AIDS clinical trials grants for the Canadian Institutes of Health Research (CIHR) (March and August, 2001)

Member of a Technical Evaluation Panel for a Contract Proposal Review for the National Institutes of Health, National Cancer Institute (August, 2002)

Member of an HIV Special Emphasis Panel to review grant applications received in response to PAR-03-095: The Integrated Preclinical/Clinical AIDS Vaccine Development Program (IPCAVD) (February 2004)

Member of the Gates Foundation Intermittent Preventive Treatment of Infants and Children for Malaria (IPTi) Review Committee (2004)

Temporary Member of the NIH AIDS Clinical Studies and Epidemiology Study Section: AIDS and Related Research Integrated Review Group (2004)

Member of the NIH AIDS Clinical Studies and Epidemiology Study Section: AIDS and Related Research Integrated Review Group (2005-2008)

Reviewer of NIH proposals for American Renewal and Recovery Act Challenge Grants (2009)

Alternate Member of the Institute of Medicine’s Study on Intermittent Preventive Therapy for Malaria in Infants (IPTi) (2008-2010)

Member of the Vaccines and Related Biological Products Advisory Committee to the Food and Drug Administration (2008-2012)

- **Selected Other Reviewer Activities**

Member of HIV Vaccine Trials Network Protocol Committee (2007-2009)

- **Advisory Boards**  
Member, U.S. Military HIV Research Program Product Development Advisory Group (2011)
- **Data Safety Monitoring Boards**  
Member of Safety Monitoring Committee for a Phase II Extended Safety Study of Tenofovir, Centers of Disease Control and Prevention (2004-2011)  
Member of Safety and Efficacy Monitoring Committee for an AIEDRP/ACTG Phase II trial of Cyclosporine A, Trizivir, and Kaletra in subjects with primary HIV infection (2005-2010)  
Member of Data and Safety Monitoring Board for an Adenovirus Serotype Vector Influenza Vaccine Phase 1 Trial (2008-2010)  
Chair, Data and Safety Monitoring Board for the FACTS 001 Phase 3 randomized trial of a microbicide gel (Truvada) to prevent HIV infection in South Africa (2011-present)
- **Associate Editor**  
Annals of Applied Statistics (2006-2010)
- **Referee for the following Journals**

<p><i>The American Journal of Epidemiology</i></p> <p><i>Annals of Applied Statistics</i></p> <p><i>The Annals of the Institute of Statistical Mathematics</i></p> <p><i>The Annals of Statistics</i></p> <p><i>Antiviral Therapy</i></p> <p><i>Biometrics</i></p> <p><i>Biometrical Journal</i></p> <p><i>Biometrika</i></p> <p><i>The Canadian Journal of Statistics</i></p> <p><i>Clinical Trials</i></p> <p><i>Communications in Statistics</i></p> <p><i>Controlled Clinical Trials</i></p> <p><i>Diagnostics</i></p> <p><i>Journal of AIDS</i></p> <p><i>Journal of the American Medical Association</i></p>	<p><i>Journal of the American Statistical Association</i></p> <p><i>Journal of Human Virology</i></p> <p><i>The Journal of Infectious Diseases</i></p> <p><i>Journal of the Royal Statistical Society B</i></p> <p><i>Journal of Statistical Planning and Inference</i></p> <p><i>The Lancet Infectious Diseases</i></p> <p><i>Lifetime Data Analysis</i></p> <p><i>PLoS Medicine</i></p> <p><i>Nature Medicine</i></p> <p><i>Nonparametric Statistics</i></p> <p><i>Scandinavian Journal of Statistics</i></p> <p><i>Statistical Communications in Infectious Diseases</i></p> <p><i>Statistics in Medicine</i></p> <p><i>Statistical Science</i></p> <p><i>Statistica Sinica</i></p>
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- **Memberships in Professional Organizations:**  
American Statistical Association  
International Biometrics Society

## 8. Bibliography

### *Refereed Research Articles*

1. DeGruttola V, Hughes M, **Gilbert PB**, Phillips A. Trial design in the era of highly effective antiviral drug combinations for HIV infection. *AIDS*. 1998;12 Suppl A:S149-56.
2. **Gilbert PB**, DeGruttola V, Hammer S. Efficient trial designs for studying combination antiretroviral treatments in patients with various resistance profiles. *J Infect Dis*. 1998;178(2):340-8.
3. **Gilbert PB**, Self SG, Ashby MA. Statistical methods for assessing differential vaccine protection against human immunodeficiency virus types. *Biometrics*. 1998;54(3):799-814.
4. Scharfstein DO, Tsiatis AA, **Gilbert PB**. Semiparametric efficient estimation in the generalized odds-rate class of regression models for right-censored time-to-event data. *Lifetime Data Anal*. 1998;4(4):355-91.
5. Christie PD, Edelberg JM, Picard MH, Foulkes AS, Mamuya W, Weiler-Guettler H, Rubin RH, **Gilbert PB**, Rosenberg RD. A murine model of myocardial microvascular thrombosis. *The Journal of Clinical Investigation*. 1999;104(5):533-39.
6. **Gilbert PB**, Lele SR, Vardi Y. Maximum likelihood estimation in semiparametric selection bias models with application to AIDS vaccine trials. *Biometrika*. 1999;86(1):27-43.
7. Renjifo B, **Gilbert PB**, Chaplin B, Vannberg F, Mwakagile D, Msamanga G, Hunter D, Fawzi W, Essex M. Emerging recombinant human immunodeficiency viruses: Uneven representation of the envelope V3 region. *AIDS*. 1999;13(13):1613-21.
8. **Gilbert PB**. Comparison of competing risks failure time methods and time-independent methods for assessing strain variations in vaccine protection. *Stat Med*. 2000;19(22):3065-86.
9. **Gilbert PB**. Some statistical issues in the design of HIV-1 vaccine and treatment trials. *Stat Methods Med Res*. 2000;9(3):207-29.
10. **Gilbert PB**. Large sample theory of maximum likelihood estimates in semiparametric biased sampling models. *Annals of Statistics*. 2000;28(1):151-94.
11. **Gilbert PB**. Developing an AIDS vaccine by sieving. *Chance*. 2000; 13:16-21.
12. **Gilbert PB**, Hanna GJ, De Gruttola V, Martinez-Picado J, Kuritzkes DR, Johnson VA, Richman DD, D'Aquila RT. Comparative analysis of HIV type 1 genotypic resistance across antiretroviral trial treatment regimens. *AIDS Res Hum Retroviruses*. 2000;16(14):1325-36.
13. **Gilbert PB**, Ribaldo HJ, Greenberg L, Yu G, Bosch RJ, Tierney C, Kuritzkes DR. Considerations in choosing a primary endpoint that measures durability of virological suppression in an antiretroviral trial. *AIDS*. 2000;14(13):1961-72.
14. Segal S, Su M, **Gilbert PB**. The effect of a rapid change in availability of epidural analgesia on the cesarean delivery rate: a meta-analysis. *Am J Obstet Gynecol*. 2000;183(4):974-78.
15. **Gilbert PB**. Interpretability and robustness of sieve analysis models for assessing HIV strain variations in vaccine efficacy. *Stat Med*. 2001;20(2):263-79.
16. **Gilbert PB**, DeGruttola V, Hammer SM, Kuritzkes DR. Virologic and regimen termination surrogate end points in AIDS clinical trials. *JAMA*. 2001;285(6):777-84.

17. **Gilbert PB**, Novitsky VA, Montano MA, Essex M. An efficient test for comparing sequence diversity between two populations. *J Comput Biol.* 2001;8(2):123-39.
18. **Gilbert PB**, Self S, Rao M, Naficy A, Clemens J. Sieve analysis: Methods for assessing from vaccine trial data how vaccine efficacy varies with genotypic and phenotypic pathogen variation. *J Clin Epidemiol.* 2001;54(1):68-85.
19. Havlir DV, Bassett R, Levitan D, **Gilbert PB**, Tebas P, Collier AC, Hirsch MS, Ignacio C, Condra J, Gunthard HF, Richman DD, Wong JK. Prevalence and predictive value of intermittent viremia with combination HIV therapy. *JAMA.* 2001;286(2):171-79.
20. Havlir DV, **Gilbert PB**, Bennett K, Collier AC, Hirsch MS, Tebas P, Adams EM, Wheat LJ, Goodwin D, Schnittman S, Holohan MK, Richman DD. Effects of treatment intensification with hydroxyurea in HIV-infected patients with virologic suppression. *AIDS.* 2001;15(11):1379-88.
21. McKeague IW, **Gilbert PB**, Kanki PJ. Omnibus tests for comparison of competing risks with adjustment for covariate effects. *Biometrics.* 2001;57(3):818-28.
22. Novitsky V, Rybak N, McLane MF, **Gilbert PB**, Chigwedere P, Klein I, Gaolekwe S, Chang SY, Peter T, Thior I, Ndung'u T, Vannberg F, Foley BT, Marlink R, Lee TH, Essex M. Identification of human immunodeficiency virus type 1 subtype C Gag-, Tat-, Rev-, and Nef-specific elispot-based cytotoxic T-lymphocyte responses for AIDS vaccine design. *J Virol.* 2001;75(19):9210-28. PMID: 114489.
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24. **Gilbert PB**, Wei LJ, Kosorok MR, Clemens JD. Simultaneous inferences on the contrast of two hazard functions with censored observations. *Biometrics.* 2002;58(4):773-80.
25. Mani I, **Gilbert PB**, Sankale JL, Eisen G, Mboup S, Kanki PJ. Inpatient diversity and its correlation with viral setpoint in human immunodeficiency virus type 1 CRF02\_AG-IbNG infection. *J Virol.* 2002;76(21):10745-55. PMID: 136616.
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28. Wu L, **Gilbert PB**. Flexible weighted log-rank tests optimal for detecting early and/or late survival differences. *Biometrics.* 2002;58(4):997-1004.
29. **Gilbert PB**, Bosch RJ, Hudgens MG. Sensitivity analysis for the assessment of causal vaccine effects on viral load in HIV vaccine trials. *Biometrics.* 2003;59(3):531-41.

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38. **Gilbert PB**. Goodness-of-fit tests for semiparametric biased sampling models. *Journal of Statistical Planning and Inference*. 2004;118(1-2):51-81.
39. **Gilbert PB**, McKeague IW, Sun Y. Tests for comparing mark-specific hazards and cumulative incidence functions. *Lifetime Data Anal*. 2004;10(1):5-28.
40. Huang CC, Barreda P, Mendoza V, Guzman L, **Gilbert PB**. A comparative analysis of abandoned street children and formerly abandoned street children in La Paz, Bolivia. *Arch Dis Child*. 2004;89(9):821-26. PMID: 1763218.
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46. **Gilbert PB**, Ackers ML, Berman PW, Francis DP, Popovic V, Hu DJ, Heyward WL, Sinangil F, Shepherd BE, Gurwith M. HIV-1 virologic and immunologic progression and initiation of antiretroviral therapy among HIV-1-infected subjects in a trial of the efficacy of recombinant glycoprotein 120 vaccine. *J Infect Dis*. 2005;192(6):974-83.
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80. **Gilbert PB**, Wu C, Jobes DV. Genome scanning tests for comparing amino acid sequences between groups. *Biometrics.* 2008;64(1):198-207.
81. Li Z, **Gilbert PB**, Nan B. Weighted likelihood method for grouped survival data in case-cohort studies with application to HIV vaccine trials. *Biometrics.* 2008;64(4):1247-55.

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83. Sun Y, Hyun S, **Gilbert PB**. Testing and estimation of time-varying cause-specific hazard ratios with covariate adjustment. *Biometrics.* 2008;64(4):1070-9.
84. Yang Y, **Gilbert PB**, Longini IM, Halloran ME. A Bayesian framework for estimating vaccine efficacy per infectious contact. *Ann Appl Stat.* 2008;2(4):1409-31. PMID: 2630256.
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#### ***Manuscripts in Press***

1. Juraska M, **Gilbert PB**. Mark-specific hazard ratio model with multivariate continuous marks: An application to vaccine efficacy (*Biometrics*), in press.
2. Huang Y, **Gilbert PB**, Wolfson J. Design and estimation for evaluating principal surrogate markers in vaccine trials (*Biometrics*), in press.
3. Tomaras GD, Ferrari G, Shen X, Alam SM, Liao H-X, Pollara J, Bonsignori M, Moody MA, Fong Y, Chen X, Nicholson C, Polin B, Zhang R, Lu X, Parks R, Kaewkungwal J, Nitayaphan S, Pitisuttithum P, Rerks-Ngarm S, **Gilbert PB**, Kim JH, Michael NL, Montefiori DC, Haynes BF. HIV-1 vaccine-induced envelope gp120 C1-region IgA mitigates binding and effector function of gp120 IgG (*PNAS*), in press.
4. **Gilbert PB**, Shepherd BE, Hudgens MG. Sensitivity analysis of per-protocol time-to-event treatment efficacy in randomized trials (*J. Am. Stat. Assoc.*), in press.
5. Janes H, Friedrich DP, Krambrink AM, Smith RJ, Kallas E, Horton H, Casimiro DR, Carrington M, Geraghty D, **Gilbert PB**, McElrath J, Frahm N. Vaccine-induced Gag-specific T cells are associated with reduced viremia after HIV infection (*J. Infect. Dis.*), in press.
6. Dai JY, Li SS, **Gilbert PB**. Case-only method for cause-specific hazards models with application to assessing differential vaccine efficacy by viral and host genetics (*Biostatistics*), in press.
7. Janes H, **Gilbert PB**, Buchbinder S, Kublin J, Sobieszczyk ME, Hammer SM. In pursuit of an HIV vaccine: Designing efficacy trials in the context of partially effective non-vaccine prevention modalities (*AIDS Res Hum Retroviruses*), in press.
8. Hertz T, Ahmed H, Friedrich DP, Casimiro DR, Self SG, Corey L, McElrath MJ, Buchbinder S, Horton H, Frahm N, Robertson MN, Graham BS, **Gilbert PB**. HIV-1 vaccine-induced T-cell responses cluster in epitope hotspots that differ from those induced in natural infection with HIV-1, (*PLOS Pathogens*), in press.

9. **Gilbert PB**, Yu X, Rotnitzky A. Optimal auxiliary-covariate based sampling design for semiparametric efficient estimation of a mean or mean difference, with application to clinical trials (Stat Med) in press.

#### **Manuscripts under Review**

1. Chiang SS, Boynton-Jarrett R, **Gilbert PB**, Juraska M, Huang C-C, and Antkowiak L. Low rates of tuberculosis screening among Bolivian mothers and children with household exposure to tuberculosis.
2. Richardson A, Hudgens MG, **Gilbert PB**, Fine JP. Nonparametric bounds and sensitivity analysis on treatment effects (Statistical Science).
3. Yates NL, Liao H-X, Fong Y, DeCamp A, Vandergrift NA, Alam SM, Ferrari G, Berman PW<sup>7</sup>, Francis D, Sinangil F, Lee C, Nitayaphan S, Rerks-Ngarm S, Kaewkungwal J, Pitisuttithum P, Tartaglia J, Zolla-Pazner S, **Gilbert PB**, Michael NL, Kim JH, Montefiori DC, Haynes BF, Tomaras GD. HIV-1 Env V1/V2 IgG3 responses correlate with decreased transmission risk in the RV144 trial and distinguish vaccine-elicited humoral responses from the VAX003 vaccine trial (Nature Medicine).
4. Gabriel E, **Gilbert PB**. Evaluating principle surrogate endpoints with time-to-event data accounting for time-varying treatment efficacy (Biostatistics).
5. **Gilbert PB**, Sun Y. Testing for vaccine efficacy against a spectrum of pathogen sequences in stratified mark-specific proportional hazards models with missing marks, with application to the RV144 HIV vaccine efficacy trial (Journal of the Royal Statistical Society Series C).
6. Liu P, Yates N, Shen X, Bonsignori M, Moody M, Liao H-X, Fong Y, Alam M, Overman G, Denny T, Ferrari G, Ochsenauber C, Kappes J, Polonis V, Pitisuttithum P, Kaewkungwal J, Nitayaphan S, Rerks-Ngarm S, Montefiori D, **Gilbert PB**, Michael N, Kim J, Haynes B, Tomaras G. Infectious virion capture by HIV-1 gp120 specific IgG from RV144 vaccinees (J Virol).
7. Fong Y, Sebestyen K, Yu X, **Gilbert PB**, Self S. nCal: A R package for nonlinear calibration (Bioinformatics).

#### **Other Refereed Scholarly Publications**

1. Workshop and report participant. Considerations regarding efficacy endpoints in HIV vaccine trials: Executive summary and recommendations of an expert panel consultation jointly organized by WHO, UNAIDS and ANRS in support of the Global HIV Vaccine Enterprise. *Vaccine*. 2009;27(14):1989-96.

#### **Books and Book Chapters**

1. **Gilbert PB** and Esparza J. HIV-1 vaccine testing, trial design, and ethics. In: *AIDS in Africa, Second Edition*, Editors M. Essex, S. M'Boup, P. Kanki, R. Marlink, S. Tlou, 2002. Kluwer Academic, New York.
2. **Gilbert PB** and Sun Y. Simultaneous inferences of HIV vaccine effects on viral load, CD4 cell counts, and antiretroviral therapy initiation in Phase 3 trials. In: *Deterministic and Stochastic Models of HIV with Intervention*, Editors W.-Y. Tan and H. Wu, 2004.
3. Cai T, **Gilbert PB**, Self S. *Cox model inferences on relative risks linked in two stages*. Cambridge, Massachusetts; Harvard University, 2004.



4. Miao X, Li X, **Gilbert PB**, Chan ISF. A multiple imputation approach for surrogate marker evaluation in the principal stratification causal inference framework. In: Risk Assessment and Evaluation of Predictions, Editors Mei-Ling Ting Lee, Mitchell Gail, Glen Satten, Tianxi Cai, Ruth Pfeiffer, Axel Gandy, 2013.

**Other Non-Refereed Published Scholarly Publications**

1. **Gilbert PB** and Bosch R. Applications of semiparametric biased sampling models to AIDS vaccine and treatment trials. Probability Theory and Mathematical Statistics, Proceedings of the 7th Vilnius Conference on Probability Theory and Mathematical Statistics, published by VSP, Utrecht, the Netherlands and TEV, Vilnius, Lithuania, 1999.
2. **Gilbert PB**, Grove D. A sequential two-stage trial design for evaluating efficacy and immune correlates for multiple vaccine regimens. HVTN News (a publication of the HIV Vaccine Trials Network), Seattle, Washington USA 2011; 3(1) 2-4. NIHMSID 356973.
3. **Gilbert PB**, DeCamp A, Edlefsen P, Magaret C, Hertz T. Sieve analysis of HIV sequences in vaccine efficacy trials. HVTN News (a publication of the HIV Vaccine Trials Network), Seattle, Washington USA, 2011;3(1) 5-7.

**9. Patents and Other Intellectual Property:** Not applicable

**10. Funding**

**Active Projects:**

5 UM1 AI068635 (Gilbert)	6/29/2006-5/31/2013
NIH/NIAID	\$7,995,909

*Leadership for HIV/AIDS Clinical Trials Networks: HIV Vaccine Trials Network*

This application to be the Statistical and Data Management Center (SDMC) describes how the Statistical Center for HIV/AIDS Research & Prevention (SCHARP) will (1) provide statistical leadership for the design, conduct, analysis and publication of Network clinical trials/studies; (2) provide central data management capability that includes randomization, data set and case report form design, central storage, security, processing and retrieval of study results; (3) provide data management and protocol training throughout the Network; (4) provide data-focused clinical trials implementation, and operation; and (5) contribute to cross-Network efforts in developing common data elements.

2 R37 AI054165 (Gilbert)	4/01/2003-3/31/2015
NIH/NIAID	\$275,572

*Statistical Methods in HIV Vaccine Efficacy Trials*

This project develops novel statistical methods for the design and analysis of preventative HIV vaccine efficacy trials and of NHP challenge trials.

W81XWH-07-2-0067 (Gilbert) 1/1/2010 – 12/31/2013  
USAMRAA (subcontract from Henry M. Jackson Foundation) \$2,907,468  
*Statistical and Data Management Support for Analysis Related to Vaccine Trial (RV144) and Associated Trials*

SCHARP will provide statistical and data management support to the USMHRP for analyses related to the Phase III HIV vaccine trial (RV144) of the ALVAC-HIV-1 (vCP1521) and AIDSVAX B/E products, conducted by the USMHRP in Thailand.

**Pending Applications:**

5 UM1 AI068635 (Gilbert) 12/1/2013-11/30/2020  
NIH/NIAID \$8,838,430

*Leadership for HIV/AIDS Clinical Trials Networks: HIV Vaccine Trials Network*

This application to be the Statistical and Data Management Center (SDMC) describes how the Statistical Center for HIV/AIDS Research & Prevention (SCHARP) will (1) provide statistical leadership for the design, conduct, analysis and publication of Network clinical trials/studies; (2) provide central data management capability that includes randomization, data set and case report form design, central storage, security, processing and retrieval of study results; (3) provide data management and protocol training throughout the Network; (4) provide data-focused clinical trials implementation, and operation; and (5) contribute to cross-Network efforts in developing common data elements.

**Previously Funded Projects:**

- “Determining Correlates of Protection Against HIV Infection” NIH-SBIR Fast Track Grant
  - \$58,000 direct costs over one year, *subcontract Principal Investigator* (2004-2005)
- HIV Vaccine Trials Network Leadership Group, Statistical Methods, NIH-NIAID, Grant 1 U01
  - AI46703-01, *co-Principal Investigator* (2000-2005)
- HIV Vaccine Trials Network Leadership Group, Statistical Methods, NIH-NIAID, Grant 2 U01
  - AI46703-06, *co-Principal Investigator* (2005-2011)
- “Statistical Methods in HIV Vaccine Efficacy Trials” NIH-NIAID, Grant 1 RO1 AI054165-01
  - \$375,000 direct costs over three years, *Principal Investigator* (2003-2006)
- “Statistical Methods in HIV Vaccine Efficacy Trials” NIH-NIAID, Grant 2 RO1 AI054165-04
  - \$700,000 direct costs over four years, *Principal Investigator* (2006-2010)
- Statistical Data Management Center for the Center for HIV/AIDS Vaccine Immunology (CHAVI) NIH/NIAID (Sub-award from Duke University) 1 U01 AI067854, Dr. Barton Haynes
  - \$1,059,612 over five years, Investigator, 10% effort (2005-2010)
- Bill & Melinda Gates Foundation, Vaccine Immunology Statistical Center (VISC), Dr. Steve Self
  - \$1,936,568 over five years, Director of Biostatistical Unit, 10% effort (2006-2011)
- NIH-NIAID, Subcontract of Seattle Biomedical Research Institute Malaria Antigen Discovery Program, Statistics and Data Center, Principal Investigator (2006-2011)
- NIH (Subaward from University of Washington) Statistical Issues in AIDS Research (2004-2014)

**11. Public Health Practice Activities:** Not applicable

## 12. Conferences and Symposiums

Mayers D, **Gilbert PB**, Merigan T for the ACTG244/RV79 Study Team. T215Y/F mutation associated with zidovudine resistance leads to poor response to ZDV+ddl or ZDV+ddl+NVP: ACTG244/RV79. In: *Program and abstracts of the Sixth Conference on Retroviruses and Opportunistic Infections*, 1999, Abstract 129.

Havlr D, **Gilbert PB**, Bennett K, Collier A, Hirsch M, Tebas P, Adams E, Holohan MK, Richman D and the ACTG 5025 Study Team. Randomized trial of continued Indinavir (IDV)/ZDV/3TC versus switch to IDV/ddI/d4T or IDV/ddI/d4T+hydroxyurea in patients with viral suppression. In: *Program and abstracts of the Seventh Conference on Retroviruses and Opportunistic Infections*, San Francisco, California (2000).

Havlr D, Levitan D, Bassett R, **Gilbert PB**, Richman D, Wong J. Prevalence and predictive value of intermittent viremia in patients with viral suppression. In: *Program and abstracts of the Fourth International Workshop on HIV-1 Drug Resistance and Treatment Strategies*, Spain (2000).

Novitsky V, Rybak N, **Gilbert PB**, Gaolekwe S, Peter T, McLane MF, Thior I, Lee TH, Ndung'u T, Marlink R, Essex M. Magnitude and frequency of CTL responses to HIV-1 subtype C. In: *Program and abstracts of the Fourteenth International AIDS Conference*, Barcelona, Spain (2002).

Renjifo B, Tanzania Vitamin and HIV Study Group, **Gilbert PB**, Chaplin B, Msamanga G, Mwakagile, Fawzi W, Essex M. Preferential in-utero transmission of HIV-1 subtype C compared to subtype A or D. In: *Program and abstracts of the Fourteenth International AIDS Conference*, Barcelona, Spain (2002).

**Gilbert PB**, De Gruttola V, Hudgens M, Self S, Hammer S, Corey L. What constitutes effectiveness for an HIV vaccine that ameliorates viremia: Issues involving surrogate endpoints in efficacy trials. In: *Abstracts of the 10<sup>th</sup> Conference on Retroviruses and Opportunistic Infections*, Boston, Massachusetts, Abstract 84 (February 2003).

**Gilbert PB**, Popovic V, Gurwith M, Francis D. Immunologic responses to rgp-120 vaccine and correlation with the risk of HIV infection- results from the world's first HIV vaccine efficacy trial. In: *Program and abstracts of AIDS Vaccine 2003*, New York, New York (2003).

Popovic V, Gurwith M, Francis D, Heyward W, Berman P, **Gilbert PB**. Evaluation of vaccine efficacy in populations with high risk behavior and high HIV incidence-results from the world's first phase III trial of HIV vaccine. In: *Program and abstracts of AIDS Vaccine 2003*, New York, New York (2003).

Popovic V, Gurwith M, Francis D, Harro C, Mayer KH, Heyward W, Berman P, **Gilbert PB**. Differential efficacy in prevention of HIV infection by rgp120 HIV-1 vaccine by gender and race – is it real? In: *Program and abstracts of AIDS Vaccine 2003*, New York, New York (2003).

Djomand G, **Gilbert PB**, Chiu Y-L, Malone S, Sullivan P, Russell N, Hammer S, Celum C, Wasserheit J. Incidence of HIV-1 breakthrough infection among participants enrolled in HIV vaccine trials from 1988 to 2002. In: *Program and abstracts of AIDS Vaccine 2003*, New York, New York (2003).

Djomand G, **Gilbert PB**, Chiu Y-L, Malone S, Sullivan P, Russell N, Hammer S, Celum C. Incidence of HIV-1 breakthrough infection among participants enrolled in HIV vaccine trials from 1988 to

2002. In: *Program and abstracts of the Second International AIDS Society Conference on HIV Pathogenesis and Treatment, Paris, France (2003)*.

Follmann D, **Gilbert PB**, Self S, Hudgens M, Gurwith M, Popovic V, Ackers M, Hu D, Flores J. An independent analysis of the effect of race in VAX004. In: *Program and abstracts of the Eleventh Conference on Retroviruses and Opportunistic Infections, San Francisco, 2004*, Abstract 106.

Shapiro R, Thior I, **Gilbert PB**, Lockman S, Wester C, Smeaton L, Stevens L, Ndung'u T, Novitsky V, van Widenfelt E, Mazonde P, Lee TH, Marlink R, Lagakos S, Essex M, and the Mashi Study Group. Maternal single-dose Nevirapine may not be needed to reduce mother-to-child transmission in the setting of maternal and infant Zidovudine and infant single-dose Nevirapine: Results of a randomized clinical trial in Botswana. In: *Program and abstracts of the Twelfth Conference on Retroviruses and Opportunistic Infections, Boston, 2005*, Abstract 74LB.

Thior I, Lockman S, Smeaton L, Shapiro R, Wester C, Heymann J, **Gilbert PB**, Stevens L, Peter T, Kim S, Makhema J, McIntosh K, Marlink R, Lagakos S, Essex M, and the Mashi Study Team. Breast-feeding with 6 months of infant Zidovudine prophylaxis vs. formula-feeding for reducing post-natal HIV transmission and infant mortality: A randomized trial in Southern Africa. In: *Program and abstracts of the Twelfth Conference on Retroviruses and Opportunistic Infections, Boston (2005)*.

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Frey SE, Peiperl L, Baden L, McElrath J, Wright P, Goepfert P, Keefer M, Blattner W, Harro C, Hammer S, Hural J, Tomaras G, Baglyos L, Guillet J-G, **Gilbert PB**, Deers M, Elizaga M, Russell N, Corey L, and the HIV Vaccine Trials Network. Immunogenicity of ANRS LIPO-5 alone, Sanofi-Pasteur ALVAC-HIV (vCP1452) alone, and ALVAC HIV prime/LIPO-5 boost in healthy, HIV-1 uninfected adult participants. In: *Program and Abstracts of AIDS Vaccine 2006, Amsterdam, The Netherlands (2006)*.

Forthal D, Landucci G, Phan T, Higa-Tanner R, **Gilbert PB**. Fcγ receptor IIa and IIIa polymorphisms are associated with risk of HIV infection. In: *Program and abstracts of the Thirteenth Conference on Retroviruses and Opportunistic Infections, Denver (2006)*.

Burke D, Karim SSA, Russel N, Wecker M, Allen M, Ferarri G, **Gilbert PB**, Chulay J. (2006). Safety and immunogenicity of an alphavirus replicon HIV Gag vaccine (AVX101) in Healthy HIV-uninfected adults. In: *Program and Abstracts of AIDS Vaccine 2006, Amsterdam, The Netherlands (2006)*.

Mehrotra D, **Gilbert PB**, Li X, Heyse J, Buchbinder S, Self S, Robertson M. (2007). A prototype test-of-concept efficacy trial design for cell mediated immunity-based vaccines. In: *Program and Abstracts of AIDS Vaccine 2007, Seattle (2007)*.

Jones N, **Gilbert PB**, DeCamp A, Peterson M, Gurwith M, Cao H. AIDSVAX immunization induces HIV-specific CD8+T cell responses in high-risk HIV negative volunteers who subsequently acquire HIV infection. In: *Program and Abstracts of AIDS Vaccine 2007, Seattle (2007)*.

- Gilbert PB.** Leveraging baseline characteristics to improve HIV prevention trials. In: *Keystone Symposium on HIV Prevention*, Keystone (2009).
- Gilbert PB.** Sieve analysis of Step sequences. *HIV Vaccine Trials Network Full Group Meeting*, Washington, D.C, May (2009).
- Gilbert PB.** Endpoints and monitoring for HVTN 505. *HIV Vaccine Trials Network Full Group Meeting*, Washington, D.C, May (2009).
- Rerks-Ngarm S, Paris RM, Chunsutthiwat S, Premisri N, Namwat C, Bowornwatanuwong J, Li S, Kaewkungkal J, Trichavaroj R, de Souza M, Francis D, Adams E, Gurunathan S, Tartaglia J, O'Connell R, Eamsila C, Nitayaphan S, Ngauy V, Thongcharoen P, Kunasol P, Michael N, Robb M, **Gilbert PB**, Kim J Extended evaluation of volunteers who become HIV-1 infected during participation in a phase III vaccine trial of ALVAC-HIV and AIDSVAX® B/E. *AIDS Vaccine 2011*. Patumwan, Bangkok, Thailand (September 2011).
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- Iyer S, Bouzek H, Kim HM, Larsen B, Casey E, Rolland M, Edlefsen P, Hertz T, Margaret C, Frahm N, Westfall D, Wong K, Zhao H, Sanders-Buell E, Tovanabutra S, Stoddard JN, Nariya S, Konopa P, Maust BS, Deng W, A. Bates A, Bradfield A, Bose M, O'Sullivan A, Hural J, Casimiro DR, Robertson MN, Michael N, McElrath MJ, Corey L, Buchbinder S, **Gilbert PB**, Kim J, Mullins JI. A deeper look at the virus populations infecting Step trial volunteers. *AIDS Vaccine 2011*. Patumwan, Bangkok, Thailand (September 2011).
- Edlefsen P, Hertz T, Margaret C, DeCamp A, **Gilbert PB**. Sieve analysis of RV144. *AIDS Vaccine 2011*. Patumwan, Bangkok, Thailand (September 2011).
- Liao H-X, Bonsignori M, Alam SM, Tomaras GD, Moody MA, Tsao C-Y, Hwang K-K, Rolland M, Mullins J, Edelfsen P, **Gilbert PB**, Lu X-Z, Parks R, Montefiori D, Ferrari G, Rao M, Karasavvas N, McLellan J, Yang Z-Y, Dai K, Pancera M, Rerks-Ngarm S, Nitayaphan S, Kaewkungwal J, Tovanabutra S, Pitisuttithum P, Tartaglia J, Sinangil F, Kim J, Michael NL, Nabel G, Mascola J, Kwong P, Pinter A, Zolla-Pazner S., Haynes BF. HIV-1 envelope antibodies induced by ALVAC-AIDSVAX B/E vaccine target a site of vaccine immune pressure within the C  $\beta$  strand of gp120 V1V2. *Keystone Symposium HIV Vaccines 2012* (January 2012).
- Rolland M, Edlefsen P, Tovanabutra S, Larsen B, Sanders-Buell E, Mullins JI, Michael NL, Kim JH, **Gilbert PB**. Sieve analysis of HIV-1 breakthrough infections in the RV144 trial. 19<sup>th</sup> International Conference on HIV Dynamics and Evolution, Ashville, North Carolina (April 2012).
- Frahm N, Tomaras G, Montefiori D, **Gilbert PB**, Corey L, McElrath MJ. Comparative immunogenicity of HIV vaccine candidates in the HVTN. *AIDS Vaccine 2012*, Boston, MA September (2012)
- Williams WB, Jones K, Krambrink A, Grove D, Liu P, Yates NL, Moody MA, Ferrari G, Pollara J, Moodie Z, Morgan CA, Liao H, Montefiori DC, Ochsenbauer C, Kappes J, Hammer S, Mascola J, Koup R, Corey L, Nabel G, **Gilbert PB**, Churchyard G, Keefer M, Graham BS, Haynes BF, Tomaras GD. Multiple antibody specificities, including gp41, V1V2, and V3 elicited in the phase II multiclade

(A,B,C) HIV-1 DNA prime, multiclade (A,B,C) rAd5 boost vaccine trial. *AIDS Vaccine 2012*, Boston, MA September (2012).

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### Meeting Posters

**Gilbert PB**. Methods for comparing genotypic resistance across antiretroviral treatment regimens from sequence data in virologic failures only. In: *AIDS Clinical Trials Group Meeting*, Washington D.C. (1998).

**Gilbert PB**. Assessing genotypic resistance in antiretroviral trials using sequence data only from virologic failures. In: *Fifth Annual HIV-1 Dynamics and Evolution Meeting*, Santa Fe, New Mexico (1998).

Novitsky V, Rybak N, McLane MF, **Gilbert PB**, Chigwedere P, Klein I, Gaolekwe S, Chang SY, Peter T, Thior I, N'dungu T, Vannberg F, Foley BT, Marlink R, Lee TH, Essex M. Predominant HIV-1C-specific CTL responses. In: *Program and abstracts of AIDS Vaccine 2001*, Philadelphia, Pennsylvania (2001).

Rossini AJ, Self SG, Hudgens M, **Gilbert PB**. Rational approach for HVTN Phase I/II HIV-1 vaccine trials. In: *Program and abstracts of AIDS Vaccine 2001*, Philadelphia, Pennsylvania (2001).

Chung M, Renjifo B, **Gilbert PB**, Msamanga G, Mwakagile, Fawzi W, Essex M. In-utero transmission of quasi-species among HIV-1 subtypes. In: *Program and abstracts of the Fourteenth International AIDS Conference*, Barcelona, Spain (2002).

**Gilbert PB**, Self S, DeGruttola V, Hudgens M, Hammer S. Interpreting observed vaccine effects on post infection surrogate endpoints in preventive HIV vaccine efficacy trials. In: *Program and abstracts of the Fourteenth International AIDS Conference*, Barcelona, Spain (2002).

Novitsky V, **Gilbert PB**, Peter T, Lee TH, Essex M. Viral load, viral diversity, and T-cell immune responses in HIV-1C infection: Implications for vaccine design. Abstracts of the 10<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Boston, Massachusetts, Abstract 458, February 2003. Novitsky V, **Gilbert PB**, Ndung'u T, Peter T, Thior I, Lee TH, Essex M. Virus-host interactions in HIV-1C infection. In: *Program and abstracts of The Fourteenth International AIDS Conference*, Bangkok, Thailand (2004).

Malone S, Djomand G, Critchlow C, **Gilbert PB**, Chiu Y-L. Risk of HIV infection among HIV vaccine and placebo control recipients enrolled in NIAID-funded network HIV vaccine trials in the United States, 1988-2002. In: *Program and abstracts of The Fourteenth International AIDS Conference*, Bangkok, Thailand (2004).

**Gilbert PB**, Cai T, Self S, Gurwith M. Joint assessment of HIV vaccine effects on preventing infection and delaying disease in the Phase III trial of AIDSVAX B/B. In: *Program and abstracts of the Eleventh Conference on Retroviruses and Opportunistic Infections*, San Francisco, 2004, Abstract 283.

- Shepherd B, **Gilbert PB**, Gurwith M, Francis D. Assessment of HIV vaccine effects on viral load in the Phase III trial of AIDSVAX B/B. In: *Program and abstracts of the Eleventh Conference on Retroviruses and Opportunistic Infections*, San Francisco, 2004, Abstract 284.
- Hudgens M, **Gilbert PB**, Wu Chih-da, Barouch D, Mascola J, Self S. Power to detect vaccine effects in repeated low-dose challenge experiments. In: *Program and Abstracts of AIDS Vaccine 2008*, Cape Town, South Africa, 2008, Poster #P03-02.
- Kunwar P, He D, Hawkins NR, Liu Y, Collier A, Hertz T, **Gilbert PB**, Horton H. Analysis of epitope-specific HIV T cell responses during early HIV-1 infection and their association with viral control. In: *Abstracts presented at AIDS Vaccine 2011*, Patumwan, Bangkok, Thailand, 2011, Poster #P01.01.
- Janes H, **Gilbert PB**, Frahm N, Rolland M, DeCamp A, Gabriel E, Wolfson J, Mullins J, McElrath J. Integrated analysis of immunogenicity, viral sequence, and viral load data in the step study. In: *Abstracts presented at AIDS Vaccine 2011*, Patumwan, Bangkok, Thailand, 2011, Poster #P01.08.
- Kijak G, Li S, Paris R, Ngaay V, Michael N, Rerks-Ngrarm S, **Gilbert PB**, Kim J. Modulation of vaccine effect by FcGamma receptor 3a genetic polymorphism in RV144. CROI 2012 (Seattle, WA).
- Defawe O, DeRosa S, Frahm N, Carter D, Fong Y, Moodie Z, Michael N, Kim J, Rerks-Ngarm S, **Gilbert PB**, McElrath J. Vaccine-induced cytokine production is associated with lower risk of HIV infection among RV144 vaccine recipients. Keystone Symposium on HIV Vaccines 2012 (Keystone, CO)
- Rolland M, Maust B, Bonsignori M, deSouza M, Edlefsen P, **Gilbert PB**, Haynes B, HwangK, KimJ, Larsen B, Liao H, Michael N, Mullins J, Nitayaphan S, Rerks-Ngarm S, Robb M, Sanders-Buell E, Tovanabuttra S, Hertz T, DeCamp A, Magaret C, Ahmed H, Juraska M, Chen L, Konopa P, Nariya S, Stoddard J, Wong K, Zhao H, Deng W, Bose M, Howell S, Lazzaro M, O'Sullivan A, Lei E, Bradfield A, Ibitanumo G, Pham D, Carlson J, Assawadarachai V, Heckerman D, Bates A. Sieve signature in the V2 target of RV144-induced antibodies. Keystone Symposium on HIV Vaccines 2012 (Keystone, CO)
- Huang Y, Self S, **Gilbert PB**, Yao L, Shao Y. U.S.-China collaborations on the design of China's first Phase IIb HIV vaccine efficacy trial. 33<sup>rd</sup> Annual Meeting of the Society for Clinical Trials. May 20-23, 2012 (Miami, FL)

#### **Selected Oral Presentations (Only includes presentations delivered by Dr. Gilbert)**

- Gilbert PB.** Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 vaccine. DIMACS International Conference on HIV-1 Sequence Variation and Statistical Methods, Rutgers University, New Brunswick, New Jersey (May 1995).
- Gilbert PB.** Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 vaccine. Biostatistics Departmental Seminar, University of California at Los Angeles, Los Angeles, California (February 1996).
- Gilbert PB.** Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 vaccine. Division of Statistics Seminar, University of California at Davis, Davis, California (February 1996).

- Gilbert PB.** Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 vaccine.' Biostatistics Departmental Seminar, University of Wisconsin, Madison, Wisconsin (March 1996).
- Gilbert PB.** Maximum likelihood estimation in semiparametric selection bias models with application to AIDS vaccine trials. Biostatistics Departmental Seminar, University of Rochester, Rochester, New York (March 1996).
- Gilbert PB.** Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 vaccine. Biostatistics Departmental Seminar, Harvard University (March 1996).
- Gilbert PB.** Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 vaccine.' Statistics Departmental Seminar, Stanford University, March 1996.
- Gilbert PB.** Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 Vaccine. Biostatistics Departmental Seminar, University of Washington, Seattle, Washington (April 1996).
- Gilbert PB.** Statistical issues in assessing secondary endpoints in HIV-1 vaccine trials. HIV-1 Vaccines for Developing Countries: Design of Efficacy Trials, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Dedham, Massachusetts (October 1996).
- Gilbert PB.** Maximum likelihood estimation in semiparametric selection bias models with application to AIDS vaccine trials. Statistics Departmental Seminar, Rutgers University (January 1997).
- Gilbert PB.** Sieve analysis: Statistical methods for assessing differential vaccine protection against HIV-1 types. ENAR, session Statistical Methods in HIV-1 Genomic Research and HIV-1 Vaccines, organized by Françoise Seillier-Moisewitsch, Memphis, Tennessee (March 1997).
- Gilbert PB.** Maximum likelihood estimation in semiparametric selection bias models with application to AIDS vaccine trials. Biostatistics Departmental Seminar, Johns Hopkins University, Baltimore, Maryland (May 1997).
- Gilbert PB.** Sieve analysis: statistical methods for assessing type-specific vaccine protection from vaccine trial data. Epidemiology and Statistics Division, National Institute of Child Health and Human Development, Rockville, Maryland (November 1997).
- Gilbert PB.** Preventive HIV-1 vaccine efficacy trial design. International Conference, HIV-1 Vaccines in Thailand: Current Progress 1998. Co-sponsored by the Harvard AIDS Institute, UNAIDS, AIDS Division of the Department of Communicable Disease Control of the Thailand Ministry of Public Health; Asean Institute for Health Development; and Center for Vaccine Development of Mahidol University, Bangkok, Thailand (February 1998).
- Gilbert PB.** Design and analysis issues for assessing viral and immune correlates of vaccine protection. HIV-1 Vaccines for developing countries: Immune Correlates of Protection, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Dedham, Massachusetts (April 1998).
- Gilbert PB.** Applications of semiparametric biased sampling models to AIDS vaccine and treatment trials. 22nd European Meeting of Statisticians; 7th Vilnius Conference on Probability Theory and



Mathematical Statistics, Session on Semiparametric Models, organized by Susan Murphy, Vilnius, Lithuania (August 1998).

**Gilbert PB.** Empirical processes and semiparametric biased sampling models. Empirical Processes in Non- and Semiparametric Statistics, Humboldt University, Berlin, Germany (August-September 1998).

**Gilbert PB.** Empirical processes and semiparametric biased sampling models. Statistics Departmental Seminar, Yale University, New Haven, Connecticut (September 1998)

**Gilbert PB.** Two randomized trial designs for studying HIV-1 vaccines in infants. HIV-1 Vaccines for Developing Countries: Vaccinating Against the Leading Infectious Killers in Children, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Dakar, Senegal (December 1998).

**Gilbert PB.** Sieve analysis. VaxGen Incorporated, Brisbane, California (April 1999).

**Gilbert PB.** Strain selection for HIV-1 vaccine design. HIV-1 Vaccines for Developing Countries: Prioritizing Vaccine Candidates for Human Trials, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Dedham, Massachusetts (October 1999).

**Gilbert PB.** Scientific issues in preventive HIV-1 vaccine efficacy trials. Second National Conference on HIV-1 and AIDS in Botswana, Gaborone, Botswana (February 2000).

**Gilbert PB.** Comparison of HIV-1 and HIV-2 infectivity from a prospective cohort study in Senegal. Fred Hutchinson Cancer Research Center, Seattle, Washington (May 2000).

**Gilbert PB.** Comparison of HIV-1 and HIV-2 infectivity from a prospective cohort study in Senegal. International Biometrics Society Meeting, San Francisco, California (July 2000).

**Gilbert PB.** Comparison of HIV-1 and HIV-2 infectivity from a prospective cohort study in Senegal. Statistics Departmental Seminar, University of British Columbia, Vancouver, Canada (November 2000).

**Gilbert PB.** Scientific issues in preventive HIV-1 vaccine efficacy trials. HIV-1 Vaccines for Developing Countries: Vaccines for Southern Africa. Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Arusha, Tanzania (December 2000).

**Gilbert PB.** Issues in primary endpoint selection in AIDS clinical trials. U.S. FDA Meeting on Endpoints for AIDS Clinical Trials, Division of AIDS, Rockville, Maryland (February 2001).

**Gilbert PB.** Sieve analysis. Harvard AIDS Institute Seminar, Harvard School of Public Health, Boston, Massachusetts (June 2001).

**Gilbert PB.** Data management in HIV-1 vaccine trials. HIV-1 Vaccines for Developing Countries: Establishing networks for HIV-1 trials in Southern Africa, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Gaborone, Botswana (November 2001).

**Gilbert PB.** Monitoring of HIV-1 vaccine efficacy trials. HIV-1 Vaccines for Developing Countries: Establishing networks for HIV-1 trials in Southern Africa, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Gaborone, Botswana (November 2001).

- Gilbert PB.** Assessing HIV vaccine effects on viral load in preventive vaccine efficacy trials. Biostatistics Departmental Seminar, University of Washington School of Public Health, Seattle, Washington (May 2002).
- Gilbert PB.** Data management for clinical trials. HIV-1 Vaccines for Developing Countries: Prospects for an HIV-1 Vaccine for West Africa, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Abuja, Nigeria (February 2003).
- Gilbert PB.** Methods for comparing mark-specific hazards and cumulative incidence functions between two groups, with application to HIV vaccine trials. International Conference on Reliability and Survival Analysis, University of South Carolina, Columbia, South Carolina (May 2003).
- Gilbert PB.** Methods for comparing mark-specific hazards and cumulative incidence functions between two groups, with application to HIV vaccine trials. Biostatistics Departmental Seminar, University of Washington School of Public Health, Seattle, Washington (June 2003).
- Gilbert PB, Shepherd B.** Sensitivity analyses comparing outcomes measured only in a subset selected post-randomization, with application to HIV vaccine trials. Genentech, San Francisco, California (January 2004).
- Gilbert PB, Shepherd B.** Sensitivity analyses comparing outcomes measured only in a subset selected post-randomization, with application to HIV vaccine trials. Department of Biostatistics, University of California San Francisco, San Francisco, California (January 2004).
- Gilbert PB.** Analysis of post-infection vaccine effects in VaxGen's two Phase 3 trials. Workshop on End Points and Regulatory Issues in HIV Vaccines and Clinical Trials, Rockville, Maryland (April 2004).
- Gilbert PB.** Surrogate and clinical endpoints for HIV vaccine efficacy trials. HIV-1 Vaccines for Developing Countries: Initiation of Vaccine Trials in Africa, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Gaborone, Botswana (May 2004).
- Gilbert PB.** Moving up the ladder in HIV vaccine trials. HIV-1 Vaccines for Developing Countries: Initiation of Vaccine Trials in Africa, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Gaborone, Botswana (May 2004).
- Gilbert PB.** Inferring dependency of HIV vaccine efficacy on HIV distance. Schering-Plough Symposium, Department of Biostatistics, Harvard School of Public Health, Boston, Massachusetts (June 2004).
- Gilbert PB.** Endpoints and analytics for Phase IIb/III HIV vaccine trials. Meeting of the External Advisory Panel on the Scientific Agenda of the HVTN, Bethesda, Maryland (September 2004).
- Gilbert PB, Shepherd B, Jemai Y, Rotnitzky A.** Sensitivity analysis comparing outcomes measured only in a subset selected post-randomization. Joint Statistical Meetings, Minneapolis, Minnesota. (August 2005).
- Gilbert PB, Hudgens M.** Comparison of group testing algorithms for identifying acute HIV-1 infections. Acute HIV-1 Infection, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Nairobi, Kenya (October 2005).

- Gilbert PB**, Forthal D. Role of FcγRIIa and FcγRIIIa genotype in risk of HIV infection and VEs. HIV Vaccine Trials Network Group Meeting, Seattle, Washington (November 2005).
- Gilbert PB**, Hudgens M. Evaluating causal effect predictiveness of candidate surrogate endpoints. Prentice Professorship Lecture, Fred Hutchinson Cancer Research Center, Seattle, Washington (May 2006).
- Gilbert PB**, Hudgens M. Evaluating causal effect predictiveness of candidate surrogate endpoints. Joint Statistical Meetings, Seattle, Washington (August 2006).
- Gilbert PB**, Qin L, Self S, A framework for evaluating immunological correlates of protection in vaccine trials. NIH/NIAID Workshop on Statistical Methods in HIV/AIDS and its Practical Application, Bethesda, Maryland (October 2006).
- Gilbert PB**, Qin L, Self S. Evaluating immunological correlates of protection. HIV Vaccine Trials Network Group Meeting, Seattle, Washington (October 2006).
- Gilbert PB**, Hudgens M. Evaluating causal effect predictiveness of surrogate endpoints, with application to HIV vaccine trials. UCLA Biostatistics Departmental Seminar, Los Angeles, California (March 2007).
- Gilbert PB**. Sieve analysis in HIV vaccine trials. First Vaccine Infectious Disease Institute Symposium, Seattle Washington (July 2007).
- Gilbert PB**. Sieve analysis for PAVE-100: Toward a statistical analysis plan. PAVE 100 Viral and Host Genetics Workshop, Vaccine Research Center, NIH, Bethesda, Maryland (July 2007).
- Gilbert PB**, McKeague I, Sun Y. Evaluating dependency of HIV vaccine efficacy on viral genetics via mark-specific hazard function modeling. Fred Hutchinson Cancer Research Center, Seattle, Washington (August 2007).
- Gilbert PB**. Molecular signatures of acutely infecting viruses. Second International Conference on HIV Transmission, Washington, D.C. (August 2007).
- Gilbert PB**. Overview of correlates and surrogates. World Health Organization workshop on HIV vaccine trial endpoints. Agence Nationale de Recherches dur le Sida (ANRS), Paris (September 2007)
- Gilbert PB**, Self S, Mehrotra D, Duerr A. Longer-term follow-up of STEP study volunteers. HIV Vaccine Trials Network Group Meeting, Seattle, Washington (November 2007).
- Gilbert PB**. Evaluating immunological correlates of protection. Center for AIDS Research Seminar, University of Washington, Seattle, Washington (December 2007).
- Gilbert PB**. Test of concept vaccine trials. Merck Vaccines, Blue Bell, Pennsylvania (April 2008).
- Gilbert PB**. Test of concept vaccine trials. University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials, Philadelphia, Pennsylvania (April 2008).
- Gilbert PB**. Test of concept vaccine trials. Division of AIDS, NIAID, NIH, Bethesda, Maryland (May 2008).
- Gilbert PB**. Assessing how vaccine efficacy depends on HIV genetics by competing risks failure time methods. Joint Statistical Meetings, Denver, Colorado (August 2008).

- Gilbert PB.** Mark-Specific proportional hazards model with missing marks. WNAR International Biometrics Society Meeting, Portland, Oregon (May 2009).
- Gilbert PB,** Sun Y. Sieve analysis of Step sequences. AIDS Vaccine Research Subcommittee, Bethesda, Maryland (June 2009).
- Gilbert PB.** What is an immune correlate? Military HIV Research Program – Thai Ministry of Public Health Immune Correlates Briefing. Bangkok, Thailand (September 2011).
- Gilbert PB.** Statistical considerations in the RV144 pilot and case control studies. Military HIV Research Program – Thai Ministry of Public Health Immune Correlates Briefing. Bangkok, Thailand (September 2011).
- Gilbert PB.** What is an immune correlate and how can it be used to guide vaccine development? Sixth Annual Meeting of the Collaboration for AIDS Vaccine Discovery (December 2011).
- Gilbert PB.** Immune correlates and sieve analysis of RV144, plus follow-up research. AIDS Vaccine Research Subcommittee, Bethesda, Maryland (January 2012)
- Gilbert PB.** Sequential phase 2b and 3 efficacy trial designs for evaluating vaccine efficacy and immune correlates for multiple HIV vaccine regimens. AIDS Vaccine Research Subcommittee, Bethesda, Maryland (January 2012)
- Gilbert PB.** Surrogate endpoints in the current era of HIV clinical trials. Clinical Trials Workshop, Nineteenth Conference on Retroviruses and Opportunistic Infections, Seattle, Washington (March 2012).
- Gilbert PB.** Statistical science perspective on the way forward.” HVTN Full Group Meeting, Washington, D.C. (May 2012).
- Gilbert PB.** A two-stage sequential phase 2b trial design for evaluating vaccine efficacy and immune correlates for multiple HIV vaccine regimens. ASA Biopharmaceutical Section FDA-Industry Statistics Workshop. Washington, DC (September 2012).
- Gilbert PB.** Evaluating vaccine efficacy and immune correlates of protection. Harvard School of Public Health-China 7<sup>th</sup> Annual HIV/AIDS Workshop “HIV/AIDS Treatment Strategies in Resource Poor Settings.” Hainan Island, China (October 2012).
- Gilbert PB.** Analytics and the SDMC. HVTN Full Group Meeting, Seattle, WA (October 2012).
- Gilbert PB.** Assessing immune correlates of protection via the vaccine efficacy curve. Webinar for the Vaccines Sub-Committee of the International Society for Clinical Biostatistics (November 2012).
- Gilbert PB.** Global acquisition sieve analysis in HIV vaccine efficacy trials. Fred Hutchinson Cancer Research Center, Vaccine and Infectious Disease Division (VIDD) Faculty Seminar (November 2012).
- Gilbert PB.** Analysis of immune correlates of protection in the RV144 HIV vaccine efficacy trial. HIV Grand Rounds CME Series and CFAR Seminar. University of Pennsylvania, Philadelphia, PA (February 2013).

**Gilbert PB.** Assessment of Treatment Efficacy in Per-Protocol and Biomarker-Response Subgroups in Randomized Placebo-Controlled Trials. Atlantic Causal Inference Conference, Cambridge, MA (May 2013).

### **13. University Service**

Center for Biostatistics in AIDS Research Statistical Computing Committee, Harvard School of Public Health, Member (1998-1999).

Department of Biostatistics Student Advising Committee, Harvard School of Public Health, Member (1998-1999).

Department of Biostatistics Committee for a Master of Science in Applied Biostatistics, Harvard School of Public Health, Member (1998-1999)

Department of Biostatistics Admissions and Recruiting Committee, Harvard School of Public Health, Member (1999-2000)

Department of Biostatistics Curriculum Committee, Harvard School of Public Health, Member (1999-2000)

Department of Biostatistics Postdoctoral Committee, Harvard School of Public Health, Member (1999-2000)

Department of Biostatistics Committee for the Summer Program in Biostatistics for Underrepresented Minority Groups, Harvard School of Public Health, Member (1999-2001)

Department of Biostatistics Diversity Committee, Harvard School of Public Health, Member (1999-2001)

Center for Biostatistics in AIDS Research Design Review Committee, Harvard School of Public Health, Member (1999-2001)

Department of Biostatistics Committee on the Future of Public Health, Harvard School of Public Health, Member (2000-2001)

Department of Biostatistics Degree Program Committee, Harvard School of Public Health, Member (2000-2001)

Department of Biostatistics Teaching Effectiveness Committee, Harvard School of Public Health, Member (2000-2001)

Department of Biostatistics Webpage Committee, Harvard School of Public Health, Member (2000-2001)

Department of Biostatistics Core Curriculum Committee, University of Washington School of Public Health, Member (2002-2004)

Department of Biostatistics Faculty Development Committee, University of Washington School of Public Health, Member (2002-2006)

Department of Biostatistics PhD Theory Exam Committee, University of Washington School of Public Health, Member (2004-2005)

Department of Biostatistics PhD Applied Exam Committee, University of Washington School of Public Health, Member (2006-2007)

Department of Biostatistics, University of Washington School of Public Health, Co-chair, Applied Exam Committee (2013-present)

Department of Biostatistics, University of Washington School of Public Health, Faculty Development Committee (2013-present)

**14. Professionally-Related Community Service:** Occasional speaker at public elementary and high schools on HIV/AIDS (1997-present)

**15. Other Pertinent Information As Needed:**

- **Fred Hutchinson Cancer Research Center Leadership Service**

Member, Executive Committee of Vaccine and Infectious Disease Division (2012-present)

Member, Steering Committee for the Interdisciplinary Training Grant (2012-present)

**16. Teaching History**

- **Formal Courses**

**Statistical Methods in Biology (DBB 207cd)**, Division of Biological Sciences, Harvard School of Public Health, 5 credits (2000)

**Regression and ANOVA in Experimental Research (Bio 211)**, Harvard School of Public Health, 5 credits (2001)

**Seminar in Biostatistics (Biostat 580)**, Department of Biostatistics, University of Washington, 1 credit (Winter 2002)

**Medical Biometry III (Biostat 513)**, Department of Biostatistics, University of Washington, 4 credits (Spring 2003)

**Evaluating Vaccine Efficacy (Biostat 578A)**, Department of Biostatistics, University of Washington, 4 credits (Winter 2006)

- **Other Teaching**

Miscellaneous guest lecturer for courses at the Harvard School of Public Health (1997-2000)

Biostatistics Consultation (Bio 312ab and Bio 312cd), Department of Biostatistics, Harvard School of Public Health (1998-1999)

- *Director of the Biostatistics Department's student consultation laboratory for two semesters*

School of Modern Statistical Methods in Medical Research, International Centre for Theoretical Physics, Trieste, Italy (1999)

- *Course developer and lecturer. Presented 4 lectures on the design and analysis of HIV-1 vaccine and antiretroviral clinical trials*

Statistics, Data Management, and Monitoring of Clinical Trials (one-week short course, Part I), Institute of Population Scientific Research, Mahidol University, Bangkok, Thailand (1999)

- *Co-course developer and lecturer. The World AIDS Foundation-funded course emphasized clinical trials for HIV-1 vaccines and treatments*

Statistics, Data Management, and Monitoring of Clinical Trials (one-week short course, Part II),  
Department of Biostatistics, Mahidol University, Bangkok, Thailand (2000)

- *Co-course developer and lecturer. The World AIDS Foundation-funded course emphasized clinical trials for HIV-1 vaccines and treatment*

Miscellaneous guest lecturer for courses at the University of Washington School of Public Health  
(Biostat 511, EPI 590B) (2004-2009)

Module on 'Immune Correlates of Vaccine-Induced Protection' at the University of Washington  
Summer Institute in Statistics and Modeling for Infectious Diseases (2009-2012)

- *Co-course developer and instructor*

Statistical Issues for HIV Vaccine Efficacy Trials. Global HIV Vaccine Enterprise Young Investigator  
Training Workshop (OCTAVE), Rio de Janeiro, Brazil and Bangkok, Thailand (2011)

- *Co-course developer and instructor for Thailand workshop*

Guest lecturer for Global Health H563/Epidemiology 549 at the University of Washington (2012)  
Workshop on Concepts and Assessment of Immune Correlates of Vaccine Protection. Center for  
Biologics Evaluation and Research (CBER), FDA, (May 2012)

- *Course developer and instructor*

- **Independent Study**

Minhee Kang, Department of Biostatistics, Harvard School of Public Health (1 semester) (2000-  
2001)

Bryan Shepherd, Department of Biostatistics, University of Washington (2 quarters) (2002)

Kenneth Wu, Department of Biostatistics, University of Washington (1 quarter) (2006)

Joanna Scott, Department of Biostatistics, University of Washington (2005-2008)

Julian Wolfson, Department of Biostatistics, University of Washington (2005-2009)

Allan DeCamp, Department of Biostatistics, University of Washington (2008-present)

Rong Fu, Department of Biostatistics, University of Washington (2012-present)

William Jen Hoe Koh, Department of Biostatistics, University of Washington (2013)

## 17. Advising and Formal Mentoring

- **PhD Dissertations, chair**

Bryan Shepherd, Department of Biostatistics, University of Washington (2002-2005)

Joanna Scott, Department of Biostatistics, University of Washington (2006-2008)

Julian Wolfson, Department of Biostatistics, University of Washington (2006-2009)

Michal Juraska, Department of Biostatistics, University of Washington (2009-2012)

Erin Gabriel, Department of Biostatistics, University of Washington (2009-2012)

Allan DeCamp, Department of Biostatistics, University of Washington (2006-present)

Rong Fu, Department of Biostatistics, University of Washington (2012-present)

- **Masters Theses, chair**

Bo Zhang, Department of Biostatistics, University of Washington (2005-2006)

- **Mentored Scientists and Postdoctoral Fellows**

Zhu Wang, Fred Hutchinson Cancer Research Center (2005-2007)

Andrew Gartland, Fred Hutchinson Cancer Research Center (2011-present)

Michal Juraska, Fred Hutchinson Cancer Research Center (2013)

- **MS and PhD committees in non-chair role**

- ***Doctoral Committee***

- Andrea Foulkes, Department of Biostatistics, Harvard School of Public Health (1998-1999)
- Raji Balasubramanian, Department of Biostatistics, Harvard School of Public Health (1999-2001)
- Sung-Kiang Chuang, Harvard School of Dental Medicine, Harvard School of Public Health (2001)
- Jinbo Chen, Department of Biostatistics, University of Washington (2002)
- Yingye Zheng, Department of Biostatistics, University of Washington (2002)
- Petra Buzkova, Department of Biostatistics, University of Washington (2004)
- Marloes Maathuis, Department of Statistics, University of Washington (2004-2006)
- Ying Huang, Department of Biostatistics, University of Washington (2006-2007)
- Leslie Taylor, Department of Biostatistics, University of Washington (2006-2008)
- Cecilia Cotton, Department of Biostatistics, University of Washington (2008-2009)
- Jessie Wu, Department of Biostatistics, University of Washington (2008-2009)
- Ken Wu, Department of Biostatistics, University of Washington (2008-2010)
- Takumi Saegusa, Department of Biostatistics, University of Washington (2010-2012)
- Tanya Granston, Department of Biostatistics, University of Washington (2009-present)
- Cheng Zheng, Department of Biostatistics, University of Washington (2012-present)
- Megan Smith, Department of Biostatistics, University of Washington (2012-present)
- Jie Hu, Department of Biostatistics, University of Washington (2013-present)

- ***Masters Committee***

- Rose Dahliwahl, Department of Pharmacy, Northeastern University (1998-1999)
- Melissa Carbine, Department of Epidemiology, University of Washington (2003-2005)
- Blythe Adamson, Department of Epidemiology, University of Washington (2009-2010)
- Richard Newman, Department of Health Services, University of Washington (2008-2010)

- ***Other Mentoring (Research Assistant Supervision)***

- Theresa Kim, Department of Biostatistics, University of Washington (2003-2004)
- Allan DeCamp, Department of Biostatistics, University of Washington (2004-2006)
- Mark Giganti, Department of Biostatistics, University of Washington (2004-2006)
- Julian Wolfson, Department of Biostatistics, University of Washington (2006-present)
- Charlotte Gard, Department of Biostatistics, University of Washington (2007)
- Yuying Jin, Department of Biostatistics, University of Washington (2007-2009)
- Michal Juraska, Department of Biostatistics, University of Washington (2009-2012)
- Erin Gabriel, Department of Biostatistics, University of Washington (2009-2012)
- Jia Jin Kee, Department of Biostatistics, University of Washington (2012-present)
- Rong Fu, Department of Biostatistics, University of Washington (2012-present)

- **Academic Advising:** Not applicable