

Curriculum Vitae: October 2014**James J. Schlesselman, Ph.D.**

Professor Emeritus, Department of Biostatistics
University of Pittsburgh Graduate School of Public Health

Education**Princeton University**

Ph.D. Statistics, 1971
M.A. Statistics, 1968
M.A. Psychology, 1968

Michigan State University

B.S. *With High Honor* (Psychology major, Mathematics minor), 1966

Membership in Professional & Scientific Societies

American Association for the Advancement of Science
American Statistical Association
Institute of Mathematical Statistics

Awards and Honors

The Kenneth E. Schuit Award (University of Pittsburgh School of Medicine Dean's Award for Master Educator), 1997
Fellow of the American College of Epidemiology, 1983
Psychometric Fellowship, Princeton University, 1966-1969
Honors College, Michigan State University, 1963-1966
Valedictorian, Lake Park High School, 1963

Research Interests

Role of statistics in scientific inference. Statistical methods for planning, monitoring, and analyzing data from clinical trials. Statistical methods for the design and analysis of epidemiologic studies.

Employment

- 2004 - 2009 Professor, Department of Biostatistics, University of Pittsburgh Graduate School of Public Health, and Director, Biostatistics Facility, University of Pittsburgh Cancer Institute; *retired on 31 July 2009.*
- 1997 - 2004 Professor, Department of Epidemiology and Public Health, University of Miami School of Medicine, and Chief, Division of Biostatistics, Sylvester Comprehensive Cancer Center
- 1992 - 1997 Professor and Chief, Division of Biostatistics, Department of Family Medicine and Clinical Epidemiology, University of Pittsburgh School of Medicine
- 1985 - 1992 Professor, Department of Preventive Medicine and Biometrics, F. Edward Hebert School of Medicine, Uniformed Services University of the Health Sciences (USUHS)
- 1981 - 1985 Associate Professor, Department of Preventive Medicine and Biometrics, F. Edward Hebert School of Medicine, USUHS
- 1976 - 1981 Chief, Biometry Branch, National Institute of Child Health and Human Development NIH/NICHD
- 1973 - 1976 Mathematical Statistician, Biometry Branch, NIH/NICHD
- 1971 - 1973 Senior Staff Fellow, Biometry Branch, NIH/NICHD
- 1969 - 1971 Commissioned Officer, United States Public Health Service, Epidemiology and Biometry Branch, NIH/NICHD

Appointments

- 2009 - *present* Professor Emeritus of Biostatistics, University of Pittsburgh
- 1993 - 2005 Adjunct Professor, Department of Preventive Medicine & Biometrics, Uniformed Services University of the Health Sciences
- 1992 - 1997 Professor, Department of Biostatistics, University of Pittsburgh Graduate School of Public Health – *secondary appointment*
- 1996 - 1997 Professor, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of Pittsburgh School of Medicine – *secondary appointment*
- 1996 - 1997 Director, Biostatistics Core, General Clinical Research Center, University of Pittsburgh Medical Center
- 1989 - 1996 Senior Associate, Department of Epidemiology, The Johns Hopkins University

Military Service

- Commissioned Officer, United States Public Health Service, 1969-1971

National & International Service

International Atomic Energy Agency (IAEA). Invited participant in a Technical Meeting concerning data-management and statistics related to clinical trials: Applied Radiation Biology and Radiotherapy Section . Vienna, Austria, May 30 - June 2, 2011.

National Cancer Institute, National Institutes of Health. Epidemiology of Cancer Study Section, Health of Populations Integrated Review Group. Chair of Special Emphasis Panel. Hendon Virginia, May 19, 2010.

National Institute on Drug Abuse (NIDA). Protocol Review Board (PRB) for NIDA's National Drug Abuse Treatment Clinical Trials Network: CTN protocol 0037 (Exercise as a Treatment for Substance Abuse Disorders). Member of PRB, July 2008 – present. Chair of Data and Safety Monitoring Board, May 2009 – 2013.

National Cancer Institute, National Institutes of Health. Epidemiology of Cancer Study Section, Health of Populations Integrated Review Group. Annapolis, MD, June 5-6, 2008.

Canada Foundation for Innovation. Reviewer for Research Hospital Fund Large-Scale Institutional Endeavours Competition. November 20, 2007.

National Cancer Institute, National Institutes of Health. Epidemiology of Cancer Study Section, Health of Populations Integrated Review Group. Baltimore, MD, June 14-15, 2007.

National Cancer Institute, National Institutes of Health. Epidemiology of Cancer Study Section, Health of Populations Integrated Review Group. Washington DC, June 29-30, 2006.

National Cancer Institute, National Institutes of Health. Epidemiology of Cancer Study Section, Health of Populations Integrated Review Group. Washington DC, June 23-24, 2005.

National Institute on Drug Abuse (NIDA). Data and Safety Monitoring Board for NIDA's National Drug Abuse Treatment Clinical Trials Network: CTN protocol 03-005 (A Two Phase Randomized Controlled Clinical Trial of Buprenorphine/Naloxone Treatment plus Individual Drug Counseling for Opioid Analgesic Dependence). Member of DSMB, April 2005 – April 2010.

National Institutes of Health. Biostatistical Methods and Research Design Study Section. Health of Populations Integrated Review Group. Washington DC, October 29, 2004.

Department of Social Medicine, University of Bristol, UK. Meeting to develop reporting guidelines for cohort, case-control, and cross-sectional studies. September 1-3, 2004.

National Cancer Institute, National Institutes of Health. Cluster review of applications in the Population Based Prevention Studies P01 Review Cluster. Bethesda, June 28-30, 2004.

Centers for Disease Control, National Immunization Program, Anthrax Vaccine Safety Activity. Meeting to advise on the design of an epidemiologic study of long-term safety of AVA vaccine. Atlanta, May 2002.

World Health Organization. Meeting on the relationship between steroid hormone contraceptive use, HPV infection and cervical cancer. Geneva, March 2002.

National Vaccine Advisory Committee, Centers for Disease Control, DHHS. Invited background paper by J. Schlesselman. Intussusception in relation to immunization with rhesus rotavirus vaccine: primer on study design. November 2001.

National Vaccine Program Office, Centers for Disease Control, DHHS. Workshop on Intussusception, Rotavirus, and Oral Vaccines. Invited presentation by J. Schlesselman: Critique of six epidemiologic studies' design, strengths, and weaknesses. Washington DC, September 2001.

UC Davis Medical Center, M.I.N.D. Institute. Scientific Advisory Panel for Epidemiology of Autism in California Study. Sacramento, November 2000.

World Health Organization. WHO Temporary Advisor for meeting on Improving Access and Quality of Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use. Geneva, March 2000.

National Institute of Child Health and Human Development, NIH. Scientific Advisory Committee for the Network for Contraceptive Research. Member, 1999 - 2006.

World Health Organization. WHO Scientific Group on Oral Contraceptives and Cardiovascular Disease. Geneva, November 1997.

University of Zimbabwe and The Johns Hopkins University. Data and Safety Monitoring Committee for a randomized clinical trial of high dose vitamin A to prevent maternal-fetal transmission of HIV. Member, 1997 - 2000.

National Institute of Child Health and Human Development, NIH. Science Advisory Committee to the NICHD Women's Contraceptive and Reproductive Experiences (CARE) Study. Member, 1996 - 1998.

National Heart, Lung, and Blood Institute, NIH. Data and Safety Monitoring Board for A Case Control Etiologic Study of Sarcoidosis (ACCESS). Member, 1996 - 2002.

National Institute of Child Health and Human Development, NIH. Advisory Committee on Steroid Contraceptives and HIV Transmission: Recommendations for Research. Bethesda, June 1996.

World Health Organization Special Programme of Research, Development and Research Training in Human Reproduction: Steering Committee of the Task Force on Epidemiological Research on Reproductive Health. Geneva: Member, 1991 - 1997.

National Institute of Child Health and Human Development, NIH. Special Review Committee for proposed clinical trial of treatment of mitochondrial myopathies with dichloroacetate. Bethesda, August 1993.

American Society for Reproductive Immunology. Special consultant for worldwide collaborative study and meta-analysis of allogeneic leukocyte immunotherapy for recurrent spontaneous abortion. Washington DC, July 1993.

International Conference on Beta-Agonists. Statistical consultant to the Department of Epidemiology and Biostatistics, McGill University School of Medicine. Montreal, January 1992.

World Health Organization. Advisory Committee on the Evaluation of Antenatal Care in Developing Countries. Geneva, November 1991.

Visiting Professor. McGill University School of Medicine, Department of Epidemiology and Biostatistics, November 1991.

World Health Organization. Workshop on Vasectomy in Relation to Cancer of the Prostate and Testis. Geneva, October 1991.

Food and Drug Administration. Workshop on Critical Issues in Medicine: Contrast Media Safety. Rockville, Maryland, June 1990.

World Health Organization. WHO Scientific Group on Oral Contraceptives and Neoplasia. Geneva, December 1990.

World Health Organization. WHO Task Force on the Safety and Efficacy of Contraceptive Methods. Geneva, October 1988.

Food and Drug Administration. Fertility and Maternal Health Drugs Advisory Committee. Rockville, Maryland: Member, 1986 - 1992.

National Research Council. Food and Nutrition Board: Subcommittee on Vitamin A. Washington DC: Member, 1986.

University of Trondheim, Department of Community Medicine and General Practice. Statistical consultant on epidemiologic studies of occupational health and prenatal care. Trondheim, Norway, September 1985.

Nutrition Center of the Philippines. Statistical consultant on a community intervention study of iron and food supplementation. Manila: June 1983, March 1984 and May 1985.

National Institute of Child Health and Human Development, NIH. Statistical consultant on vaccine field trials. Bethesda: 1981 - 1991.

Postgraduate Institute of Medical Education and Research. WHO invited lecturer in biostatistics. Chandigarh, India, October 1979.

Agency for International Development. Statistical consultant on a sample survey and clinical trial of vitamin A supplementation to treat and prevent xerophthalmia. Jakarta, Indonesia, June 1979.

Institute of Nutrition of Central America and Panama. Statistical consultant on a community intervention study of protein/calorie supplementation and mental development. Guatemala City, Guatemala: June 1976 and July 1978.

Chulalongkorn University Institute of Health Research. WHO Special Adviser on epidemiologic and clinical studies of hormonal contraception. Bangkok, Thailand: October 1975, November 1976 and November 1979.

Centers for Disease Control, Division of Reproductive Health, Epidemiologic Studies Branch. Statistical consultant on epidemiologic studies of contraceptive methods, 1979 - 1985.

Institute of Mother and Child. Statistical consultant on a follow-up study of sequelae of induced abortion. Warsaw, Poland, October 1976.

National Institute of Child Health and Human Development, NIH. Chief of Biometry Branch: design, coordinate, and analyze collaborative clinical trials conducted by the NICHD. Bethesda: 1974 - 1981.

Gerontology Research Center. Statistical consultant on longitudinal study of human aging in males. Baltimore, Maryland: 1969 - 1974.

Editorship

American Journal of Epidemiology. Associate Editor, 1982-1988.

Peer Reviews

American Journal of Epidemiology, Archives of Pediatrics & Adolescent Medicine, Biometrical Journal, British Medical Journal, Cancer Causes and Control, Controlled Clinical Trials, Clinical Trials, European Journal of Cancer, Human Reproduction, Journal of the American Medical Association, Journal of Clinical Epidemiology, Journal of Clinical Oncology, Lancet, Obstetrics & Gynecology, Preventive Medicine, Statistics in Medicine.

Books

Schlesselman, JJ. *Case-Control Studies: Design, Conduct, Analysis*. New York: Oxford University Press, 1982, xv + 354 pp. (in Japanese translation, 1985)

Articles

Raez LE, Papadopoulos K, Ricart AD, Chiorean EG, Dipaola RS, Stein MN, Rocha Lima CM, Schlesselman JJ, Tolba K, Langmuir VK, Kroll S, Jung DT, Kurtoglu M, Rosenblatt J, Lampidis TJ. A phase I dose-escalation trial of 2-deoxy-D-glucose alone or combined with docetaxel in patients with advanced solid tumors. *Cancer Chemother Pharmacol*. 2013 Feb;71(2):523-30.

Mehta DR, Foon KA, Redner RL, Raptis A, Agha M, Hou JZ, Duggal S, Luong TM, Schlesselman JJ, Boyiadzis M. Fludarabine and cytarabine in patients with acute myeloid leukemia refractory to two different courses of front-line chemotherapy. *Leuk Res* 2011 Jul;35(7):885-8. Epub 2011 Feb 18.

McHayleh W, Foon K, Redner R, Sehgal R, Raptis A, Agha M, Luong TM, Schlesselman JJ, Boyiadzis M. Gemtuzumab ozogamicin as first-line treatment in patients aged 70 years or older with acute myeloid leukemia. *Cancer* 2010 Jun 15;116(12):3001-5.

McHayleh W, Sehgal R, Redner RL, Raptis A, Agha M, Natale J, Luong TM, Schlesselman JJ, Foon KA, Boyiadzis M. Mitoxantrone and etoposide in patients with newly diagnosed acute myeloid leukemia with persistent leukemia after a course of therapy with cytarabine and idarubicin. *Leuk Lymphoma* 2009 Nov;50(11):1848-53.

Brell JM, Matin K, Evans T, Volkin RL, Kiefer GJ, Schlesselman JJ, Dranko S, Rath L, Schmotzer A, Lenzner D, Ramanathan RK. Phase II study of docetaxel and gefitinib as second-line therapy in gemcitabine pretreated patients with advanced pancreatic cancer. *Oncology*. 2009; 76(4):270-274. Epub Mar 4.

Epperly MW, Dixon T, Wang H, Schlesselman J, Francicola D, Greenberger JS. Modulation of radiation-induced life shortening by systemic intravenous MnSOD-plasmid liposome gene therapy. *Radiat Res*. 2008 Oct;170(4):437-43.

Vandenbroucke JP, von Elm E, Altman DG, Gotzsche PC, Mulrow CD, Pocock SJ, Poole C, Schlesselman JJ, Egger M; for the STROBE Initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration. *Ann Intern Med* 2007 Oct 16;147(8):W163-94. *Note: this article was also published in Epidemiology 2007;18:805-835; PLoS Medicine 2007;4:e297; Gaceta Sanitaria [in Spanish] 2009 Mar-Apr;23(2):158. Epub 2009 Feb 26.*

Schlesselman JJ. The emerging case-control study: lung cancer in relation to tobacco smoking. *Prev Med.* 2006 Oct;43(4):251-5. Epub 2006 Sep 25.

Schlesselman JJ, Reis IM. Phase II clinical trials in oncology: strengths and limitations of two-stage designs. *Cancer Invest.* 2006 Jun-Jul;24(4):404-12.

Singal R, Das PM, Manoharan M, Reis IM, Schlesselman JJ. Polymorphisms in the DNA methyltransferase 3b gene and prostate cancer risk. *Oncol Reports* 2005; Aug;14(2): 569-73.

Singal R, Ferdinand L, Das PM, Reis IM, Schlesselman JJ. Polymorphisms in the methylenetetrahydrofolate reductase gene and prostate cancer risk. *Int J Oncol* 2004; 25(5):1465-71.

Singal R, Ferdinand L, Reis IM, Schlesselman JJ. Methylation of multiple genes in prostate cancer and relationship with clinicopathological features of disease. *Oncol Reports* 2004; 12:631-7.

Raez LE, Cassileth PA, Schlesselman JJ, Sridhar K, Padmanabhan S, Fisher EZ, Baldie PA, Podack ER. Allogeneic vaccination with a B7.1 HLA-A gene-modified adenocarcinoma cell line in patients with advanced non-small-cell lung cancer. *J Clin Oncol* 2004; 22:2800-7.

Burkman R, Schlesselman JJ, Ziemann M. Safety concerns and health benefits associated with hormonal contraception. *Am J Obstet Gynecol* 2004;190:S5-22.

Raez LE, Cassileth PA, Schlesselman JJ, Padmanabhan S, Fisher EZ, Baldie PA, Sridhar K, Podack ER. Induction of CD8 T-cell-Ifn- γ response and positive clinical outcome after immunization with gene-modified allogeneic tumor cells in advanced non-small-cell lung carcinoma. *Cancer Gene Therapy* 2003; 10:850-8.

Schlesselman JJ, Collins JA. Evaluating systematic reviews and meta-analyses. *Seminars in Reproductive Medicine* 2003; 21:95-105.

Sofer M, Hamilton-Nelson KL, Schlesselman JJ, Soloway MS. Risk of positive margins and biochemical recurrence in relation to nerve-sparing radical prostatectomy. *J Clin Oncol* 2002; 20:1853-58.

Walker GR, Schlesselman JJ, Ness RB. Family history of cancer, oral contraceptive use, and ovarian cancer risk. *Am J Obstet Gynecol* 2002; 186:8-14.

Collins JA, Schlesselman JJ. Perimenopausal use of reproductive hormones: effects on breast and endometrial cancer. *Obstet Gynecol Clin North Am* 2002; 29:511-25.

Ness RB, Grisso JA, Klapper J, Schlesselman JJ, Silberzweig S, Vergona R, Morgan M, Wheeler JE, and the SHARE Study Group. Risk of ovarian cancer in relation to estrogen and progestin dose and use characteristics of oral contraceptives. *Am J Epidemiol* 2000;152:233-241.

Mies C, Schlesselman JJ. Detection of "occult" lymph node metastasis in breast cancer: Should pathologists go the extra mile? *Adv Anatomic Pathol* 2000;7:149-152.

Ness RB, Grisso JA, Cottreau C, Klapper J, Vergona R, Wheeler JE, Morgan M, Schlesselman JJ. Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer. *Epidemiology* 2000;11:111-117.

Collins JA, Schlesselman JJ. Hormone replacement therapy and endometrial cancer. In Lobo R ed. *Treatment of the Postmenopausal Woman: Basic and Clinical Aspects, 2nd edition.* New York: Lippincott-Raven, 1999: 503-511.

Farley TMM, Collins J, Schlesselman JJ. Hormonal contraception and risk of cardiovascular disease: an international perspective. *Contraception* 1998; 57:211-230.

Zimmerman RK, Schlesselman JJ, Mieczkowski TA, Medsger AR, Raymund M. Physician concerns about vaccine side effects and potential litigation. *Arch Pediatr Adolesc Med* 1998; 152:12-19.

WHO Scientific Group (includes J. Schlesselman). Cardiovascular Disease and Steroid Hormone Contraception. WHO Technical Report Series 887. Geneva: World Health Organization, 1998, 89 pp.

Schlesselman JJ, Collins JA. The influence of steroids on gynecologic cancers. In Fraser IS, Jansen RPS, Lobo RA, Whitehead MI, eds. *Estrogens and Progestogens in Clinical Practice*. London: Churchill Livingstone, 1998: 831-864.

Schlesselman JJ. Risk of endometrial cancer in relation to use of combined oral contraceptives. A Practitioner's Guide to Meta-analysis. *Hum Reprod* 1997;12:1851-1863.

Zimmerman RK, Schlesselman JJ, Baird AL, Mieczkowski TA. A national survey to understand why physicians defer childhood immunizations. *Arch Pediatr Adolesc Med* 1997;151:657-664.

Schlesselman JJ. Biostatistics in epidemiology: a view from the faultline. *J Clin Epidemiol* 1996;49:627-629.

Mishell, Jr. DR, Carr BR, Comp PC, Kaunitz AM, Ory HW, Schlesselman JJ, Sulak PJ. Estrogen Doses of Oral Contraceptives: What Are the Choices? *Dialogues in Contraception* 1996;4:1-12.

Expert Panel (includes J. Schlesselman). Principles for Evaluating Epidemiologic Data in Regulatory Risk Assessment. Washington DC: Federal Focus, 1996, 124 pp.

Schlesselman JJ. Net effect of oral contraceptive use on the risk of cancer in women in the United States. *Obstet Gynecol* 1995;85:793-801.

The Recurrent Miscarriage Immunotherapy Trialists Group (writing committee: Coulam CB, Clark DA, Collins J, Scott JR, Schlesselman JJ). Worldwide collaborative observational study and meta-analysis on allogeneic leukocyte immunotherapy for recurrent spontaneous abortion. *Amer J Reprod Immunol* 1994;32:55-72.

Gross TP, Schlesselman JJ. The estimated effect of oral contraceptive use on the cumulative risk of epithelial ovarian cancer. *Obstet Gynecol* 1994;83:419-24.

Gross TP, Schlesselman JJ, Stadel BV, Yu W, Lee NC. The risk of epithelial ovarian cancer in short-term users of oral contraceptives. *Am J Epidemiol* 1992;136:46-53.

Schlesselman JJ, Stadel BV, Korper M, Yu W, Wingo PA. Breast cancer detection in relation to oral contraception. *J Clin Epidemiol* 1992;45:449-59.

WHO Scientific Group (includes J. Schlesselman). Oral Contraceptives and Neoplasia. WHO Technical Report Series 817. Geneva: World Health Organization, 1992, 46 pp.

Greenland S, Maclure M, Schlesselman JJ, Poole C, Morgenstern H. Standardized regression coefficients: a further critique and review of some alternatives. *Epidemiology* 1991;2:387-92.

Schlesselman JJ. Oral contraceptives and neoplasia of the uterine corpus. *Contraception* 1991;43:557-79.

Speroff L, Haney A, Lippman M, Schlesselman JJ. Role of hormones in breast cancer risk. *Contemporary OB/GYN* 1991;36:80-95.

Schlesselman JJ. Oral contraceptives and breast cancer. *Am J Obstet Gynecol* 1990;163:1379-87.

Schlesselman JJ. Breast cancer and the contraceptive pill: What is the current thinking? *Medical Dialogue* 1990;283:1-4.

Wingo PA, Lee NC, Ory HW, Layde PM, Webster LA, Rubin GL, Sattin RW, Stadel BV, Schlesselman JJ. Oral contraceptives and the risk of breast cancer. In Mann RD, ed. *Oral Contraceptives and Breast Cancer*. Carnforth: Parthenon 1990:67-84.

Schlesselman JJ. Oral contraceptives in relation to cancer of the breast and reproductive tract: an epidemiological review. *Br J Fam Planning* 1989;15:23-33.

Westin S, Schlesselman JJ, Korper M. Long-term effects of a factory closure: unemployment and disability during ten years' follow-up. *J Clin Epidemiol* 1989;42:435-41.

Schlesselman JJ. Cancer of the breast and reproductive tract in relation to use of oral contraceptives. *Contraception* 1989;40:1-38.

Murray PP, Stadel BV, Schlesselman JJ. Oral contraceptive use in women with a family history of breast cancer. *Obstet Gynecol* 1989;73:977-83.

Grimes DA, Mishell DR, Schlesselman JJ, Stadel BV. OCs and breast cancer: a roundtable discussion. *Dialogues in Contraception* 1989;2:1-8.

Stadel BV, Lai SH, Schlesselman JJ, Murray P. Oral contraceptives and premenopausal breast cancer in nulliparous women. *Contraception* 1988;38:287-99.

Westin S, Norum D, Schlesselman JJ. Medical consequences of a factory closure: illness and disability in a four-year follow-up study. *Int J Epidemiol* 1988;17:153-61.

Schlesselman JJ, Stadel BV, Murray P, Lai SH. Breast cancer in relation to early use of oral contraceptives: no evidence of a latent effect. *J Am Med Assoc* 1988;259:1828-33.

Schlesselman JJ, Stadel BV, Murray P, Lai SH. Breast cancer risk in relation to type of estrogen contained in oral contraceptives. *Contraception* 1987;36:595-613.

Schlesselman JJ, Stadel BV, Murray P, Wingo PA, Rubin GL. Consistency and plausibility in epidemiologic analysis: An application to breast cancer in relation to use of oral contraceptives. *J Chron Dis* 1987;40:1033-9.

Schlesselman JJ. "Proof" of cause and effect in epidemiologic studies: criteria for judgment. *Prev Med* 1987;16:195-210.

Schlesselman JJ, Stadel BV. Exposure opportunity in epidemiologic studies. *Am J Epidemiol* 1987;125:174-8.

Gahl WA, Reed GF, Thoene JG, Schulman JD, Rizzo WB, Jonas AJ, Denman DW, Schlesselman JJ, Corden BJ, Schneider JA. Cysteamine therapy for children with nephropathic cystinosis. *N Engl J Med* 1987;316:971-7.

Schneerson R, Robbins JB, Parke JC, Bell C, Schlesselman JJ, Sutton A, Wang Z, Schiffman G, Karpas A, Shiloach J. Quantitative and qualitative analyses of serum antibodies elicited in adults by *Haemophilus influenzae* type b and pneumococcus type 6A capsular polysaccharide-tetanus toxoid conjugates. *Infect Immun* 1986;52:519-28.

Stadel BV, Schlesselman JJ. Oral contraceptive use and the risk of breast cancer in women with a "prior" history of benign breast disease. *Am J Epidemiol* 1986;123:373-82.

Greenland S, Schlesselman JJ, Criqui MH. The fallacy of employing standardized regression coefficients and correlations as measures of effect. *Am J Epidemiol* 1986;123:203-8.

Stadel BV, Rubin GL, Webster LA, Schlesselman JJ, Wingo PA. Oral contraceptives and breast cancer in young women. *Lancet* 1985;ii:970-3.

Schlesselman JJ. Valid selection of subjects in case-control studies. *J Chron Dis* 1985;38:549-50.

Schlesselman JJ. Characteristics of case-control studies. In ten Kate LP, Pearson PL, Stadhouders AM, eds. *Research into the Origin and Treatment of Duchenne Muscular Dystrophy*. Amsterdam: Excerpta Medica, 1984:53-68.

Denman DW, Schlesselman JJ. Interval estimation of the attributable risk for multiple exposure levels in case-control studies. *Biometrics* 1983;39:185-92.

Layde PM, Webster LA, Wingo PA, Schlesselman JJ, Ory HW. Long-term oral contraceptive use and the risk of breast cancer. *J Am Med Assoc* 1983;249:1591-5.

Brittain E, Schlesselman JJ. Optimal allocation for the comparison of proportions. *Biometrics* 1982;38:1003-10.

Wynder EL, Schlesselman JJ, Wald N, Lilienfeld A, Stolley PD, Higgins ITT, Radford E. Weak associations in epidemiology and their interpretation. *Prev Med* 1982;11:464-76.

Layde PM, Ory HW, Schlesselman JJ. The risk of myocardial infarction in former users of oral contraceptives. *Persp Fam Plan* 1982;14:78-80.

Brittain E, Schlesselman JJ, Stadel BV. Cost of case-control studies. *Am J Epidemiol* 1981;114:234-43.

Dixon G, Schlesselman JJ, Ory HW, Blye RP. Ethinylestradiol and conjugated estrogens as postcoital contraceptives. *J Am Med Assoc* 1980;244:1336-9.

Corash L, Spielberg S, Bartsocas C, Boxer L, Steinberg R, Sheetz M, Egan M, Schlesselman JJ, Schulman JD. Reduced chronic hemolysis during high dose vitamin E administration in Mediterranean type glucose-6-phosphate dehydrogenase deficiency. *N Engl J Med* 1980;303:416-20.

Stadel BV, Sternthal PS, Schlesselman JJ, Hall DW, Ahuwahlia B. Variation of ethinyl estradiol blood levels among healthy women using oral contraceptives. *Fertil Steril* 1980;33:257-60.

Schlesselman JJ. How does one assess the risk of abnormalities from human in vitro fertilization? *Am J Obstet Gynecol* 1979;134:135-48.

Schneider JA, Schlesselman JJ, Mendoza SA, Orloff S, Thoene JG, Kroll WA, Godfrey AD, Schulman JD. Ineffectiveness of ascorbic acid therapy in nephropathic cystinosis. *N Engl J Med* 1979;300:756-9.

- Schlesselman JJ. Assessing effects of confounding variables. *Am J Epidemiol* 1978;108:3-8.
- Schlesselman JJ. The effect of errors of diagnosis and frequency of examination on reported rates of disease. *Biometrics* 1977;33:635-42.
- Parke JC, Schneerson R, Robbins JB, Schlesselman JJ. Interim report of a controlled field trial of immunization with capsular polysaccharides of *Haemophilus influenzae* type b and group c *neisseria meningitidis* in Mecklenburg County, North Carolina, (March 1974/March 1976). *J Infect Dis* 1977;136:551-6.
- Fjellstedt TA, Schlesselman JJ. A simple statistical method for use in kinetic analysis based on Lineweaver-Burk plots. *Anal Biochem* 1977;80:224-38.
- Byar DP, Simon RM, Friedewald WT, Schlesselman JJ, DeMets DL, Ellenberg JH, Gail MH, Ware JH. Randomized clinical trials: perspectives on some recent ideas. *N Engl J Med* 1976;295:74-80.
- Whisnant J, Rogentine G, Gralnick M, Schlesselman JJ, Robbins J. HL-A antigens, erythrocyte antigens, and serum anti-capsular antibodies in patients with *Haemophilus influenzae* type b diseases. *J Infect Dis* 1976;133:448-55.
- Schlesselman JJ, Spiers P. Anencephaly, spina bifida and dizygotic twinning: a review of the data of Stevenson et al. *Am J Epidemiol* 1975;101:14-6.
- Spiers P, Schlesselman JJ, Wright S. Sudden infant death syndrome in the United States: a study of geographic and other variables. *Am J Epidemiol* 1974;100:380-9.
- Schlesselman JJ. Sample size requirements in cohort and case-control studies of disease. *Am J Epidemiol* 1974;99:381-4.
- Schlesselman JJ. Planning a longitudinal study. II. Frequency of measurement and study duration. *J Chron Dis* 1973;26:561-70.
- Schlesselman JJ. Planning a longitudinal study. I. Sample size determination. *J Chron Dis* 1973;26:553-60.
- Schlesselman JJ. Data transformation in two-way analysis of variance. *J Am Stat Assoc* 1973;68:369-78.
- Chez R, Schlesselman JJ, Salazar H, Fox R. Single placentas in the rhesus monkey. *J Med Primatology* 1972;1:230-40.
- Schlesselman JJ. Power families: a note on the Box and Cox transformation. *J Royal Stat Soc, Series B*, 1971;33:307-11.

Book Reviews

- Schlesselman JJ. Sexual Chemistry: a history of the contraceptive pill. *BMJ* 2001; 323:171.

Letters

- Schlesselman JJ. The Devi case and more. *Science* 1995;269:1034.

Stadel BV, Schlesselman JJ, Murray PM. Oral contraceptives and breast cancer. *Lancet* 1989;1:1257-8.

Schlesselman JJ, Stadel BV. In reply: Latent effect of oral contraceptives on breast cancer. *J Am Med Assoc* 1988;260:1240-1.

Schlesselman JJ, Stadel BV. Oral contraceptives and breast cancer. *Lancet* 1987;2:383.

Stadel BV, Schlesselman JJ. Oral contraceptives and breast cancer. *Lancet* 1986;2:922-3.

Stadel BV, Rubin GL, Wingo PA, Schlesselman JJ. Oral contraceptives and breast cancer in young women. *Lancet* 1986;1:436.

Schlesselman JJ. In reply: Assessing effects of confounding variables. *Am J Epidemiol* 1980;111:128-9.

Invited Courses

Schlesselman JJ. Phase II clinical trials: the bridge to pivotal studies. 2nd International Biometric Society Conference of the Eastern Mediterranean Region. Antalya, Turkey, January 12, 2003.

Schlesselman JJ. Design of Clinical Trials. Department of Biostatistics, University of Pittsburgh Graduate School of Public Health, June 4-12, 1998.

Caritis S, Ness R, Schlesselman JJ. Clinical Epidemiology Applied to Maternal-Fetal Medicine. Magee-Womens Hospital, Pittsburgh, April 14 - June 2, 1994.

Schlesselman JJ. The Conduct and Interpretation of Case-Control Studies. The University of Michigan School of Public Health. International Graduate Summer Session in Epidemiology, July 7-26, 1991.

Schlesselman JJ. Statistical Methods for Epidemiologic Studies. Children's Castle Hospital, Helsinki, Finland, June 8-12, 1987.

Schlesselman JJ. Design and Analysis of Epidemiologic Studies. Institute of Basic Medical Sciences, Chinese Academy of Medical Sciences, Beijing, China, April 15-19, 1985.

Schlesselman JJ. Design and Analysis of Medical Investigations in Clinical Practice. University of Oslo, Norway, October 3-4, 1983.

Schlesselman JJ. Case-Control Studies. University of Trondheim, Norway, September 25-30, 1983.

Invited Talks (since 1990)

Statistical perspective on disease screening and treatment effectiveness. Osher Lifelong Learning Institute at Carnegie Mellon University, Pittsburgh. September 13, 2011 & May 9, 2012.

Biostatistics in Observational and Experimental Studies. Summer Institute for Training in Biostatistics. University of Pittsburgh Graduate School of Public Health, Pittsburgh, June 23, 2011.

Statistical Methods in Medical Research: Does Treatment Help or Harm? Osher Lifelong Learning Institute at Carnegie Mellon University, Pittsburgh. November 17, 2010 & May 11, 2011.

Multiple Comparisons in Epidemiology. Peking Union Medical College, Beijing, China. May 30, 2007.

Clinical Trials in Translational Research - The Bridge from Laboratory-Based Science to Clinical Applications. The 1st Asian-Pacific Summit on Emerging Healthcare Strategy. (Organized by the Chinese Academy of Medical Sciences, Peking Union Medical College, and Mayo Clinic College of Medicine.) Beijing, China. May 26-29, 2007.

Cytochlor - protocol development for a phase I study. Fox Chase Cancer Center, Philadelphia, June 12, 2003.

Screening for HPV infection in women seeking oral contraception: estimated effects on cervical cancer, unintended pregnancies, and maternal mortality in countries worldwide. 2nd International Biometric Society Conference of the Eastern Mediterranean Region. Antalya, Turkey, January 14, 2003.

The Story of C. Mayo Clinic. Rochester, MN. September 24, 2002.

Statistics in Biomedical Inference. Mayo Clinic. Rochester, MN. September 23, 2002.

Neoplastic Effects of Hormonal Contraceptives. National Institute of Child Health and Human Development, NIH, Bethesda, MD. Symposium on Preventing Unintended Pregnancy: Advances in Hormonal Contraception, June 11-12, 2001.

Statistics in Biomedical Inference. American Statistical Association, Princeton-Trenton Chapter, Princeton University, June 16, 2000.

Study Designs in Clinical Research. Mount Sinai Medical Center, Miami Beach, FL, September 14, 1999.

Biostatistics in Clinical Research. Center for Clinical Pharmacology, University of Pittsburgh Medical Center, November 24-25, 1997.

Randomized Clinical Trials. Biometry Facility, University of Vermont, November 19, 1996

Case-Control Studies. St. Margaret's Hospital, Residency Program in Family Medicine, Pittsburgh, PA, August 8, 1996.

Meta-Analysis of Cancer Risk Associated with Use of Oral Contraceptives in U.S. Women. Department of Biostatistics, University of Pittsburgh, Pittsburgh, PA, March 18, 1995.

Use of Statistics in Planning Biomedical Studies. Department of Mathematics and Statistics, University of Pittsburgh, Pittsburgh, PA, November 11, 1993.

Net Effect of Oral Contraceptives on Cancer of the Breast and Reproductive Tract. International Symposium on Reproductive Epidemiology and Social Science Research, Chengdu, China, October 11-13, 1993.

Biostatistics in Epidemiology. Pittsburgh Statistical Society Annual Meeting, Pittsburgh, PA, May 13, 1993.

Oral Contraceptives and Breast Cancer. Eastern Virginia Medical School, Current Topics in Reproductive Endocrinology and Gynecology Conference, Falls Church, VA, April 3-4, 1992.

Is There Biased Detection of Breast Cancer in Women Using Oral Contraceptives? U.S. Food and Drug Administration, Center for Drug Evaluation Research, Rockville, MD, April 1, 1992.

Biostatistics in Epidemiology: A View from the Faultline. Society for Epidemiologic Research, 24th Annual Meeting, Buffalo, NY, June 11-14, 1991.

Oral contraceptives and Breast Cancer: Issues Related to Age, Duration of Use, Dose, and Latent Effects. The Institute of Medicine. Conference on the Relationship Between Oral Contraceptives and Breast Cancer, Irvine, California, May 3-4, 1990.

Breast Cancer and the Contraceptive Pill. Georgetown University Medical Center, Vincent T. Lombardi Cancer Research Center, Washington, DC, Sept 14, 1990.

Multivariate Analysis. The Johns Hopkins University, Department of Epidemiology, April 16, 1990.

Ph.D. Committees

Phyllis A. Wingo. Five-year survival in women with breast cancer according to prior use of oral contraceptives. Member, Dissertation Committee for PhD in Biostatistics, Emory University School of Public Health, 1992-1993.

Daniel Feaster. The effect of attrition on estimated parameters of a model of CD4 cell count decline in HIV infection. Co-chair, Dissertation Committee for PhD in Biostatistics (Inter-Departmental Program), University of Miami, 1998 - 2000.

Hong Lai. Clinical Implications of Mutations in the p53 Tumor Suppressor Gene in Female Patients with Breast Cancer. Member, Dissertation Committee for PhD in Epidemiology, University of Miami, Department of Epidemiology and Public Health, 2000 - 2001.

Fengchao Ma. Cancer Incidence and General Mortality in a Cohort of Florida Firefighters. Member, Dissertation Committee for PhD in Epidemiology, University of Miami, Department of Epidemiology and Public Health, 1999 - 2003.

Master's Degree Committees

Ahmad A. Tarhini, MD. Safety and Immunogenicity of Vaccination with Multi-Epitope Peptide Vaccine Containing MART-1, gp100, and Tyrosinase Peptides given with the Combination of GMCSF and CpG Oligonucleotide (CpG 7909) in ISA-Oil Adjuvant for Patients with Recurrent Inoperable Stage III or Stage IV Melanoma. Member, Thesis Committee for MSc in Clinical Research, University of Pittsburgh School of Medicine, 2005-2006.

Mentoring of Graduate Students

Ahmad A. Tarhini MD, MSc, doctoral candidate in Clinical and Translation Science, University of Pittsburgh School of Medicine, 2008 – 2009.

The-Minh Luong, doctoral candidate in Biostatistics, University of Pittsburgh Graduate School of Public Health (GSPH), University of Pittsburgh, 2006 – 2009.

Yongyun Zhao, doctoral candidate in Biostatistics, GSPH, University of Pittsburgh, 2005 – 2006.

Beth Zamboni, doctoral candidate in Biostatistics, GSPH, University of Pittsburgh, 2004 – 2006.

Courses Taught

Clinical Trials: Methods and Practice. Developed and taught a spring-semester 2006 course on clinical trials (BIOST 2062) in the Department of Biostatistics, University of Pittsburgh Graduate School of Public Health. This course presents principles that underlie the design of clinical trials, and statistical methods and computer software that can be used in planning such studies and analyzing data from them. To achieve its aims, the course uses lectures, case studies, classroom discussions, written assignments, and problems for solution. Students learn design principles for phase I, phase II, and phase III clinical trials, including cross-over studies, bioequivalence studies, and community intervention trials. Through classroom discussion of written protocols and published clinical trials, students learn how to write a protocol for a clinical trial, justify the design and sample size for these investigations, present plans for the statistical analysis of the resulting data, and propose how study progress should be monitored. Students also learn basic methods for the analysis of cross-over studies and survival analysis for parallel-group studies, some of the requirements for sound data management, and ethical considerations that arise in planning and conducting human investigations. Active participation in classroom discussions, timely completion of assigned problems, well-prepared presentations in class, and the development of a brief protocol for a clinical trial (term paper) are required for successful completion of the course.

Clinical Trials. Developed and taught in Winter Term a three-credit course (EPH604) for graduate students in epidemiology and biostatistics. Students learned principles that underlie the design of clinical trials, practical and ethical problems that arise in human investigations, and statistical methods and computer software for planning clinical trials and analyzing data from them. The course covered the design and analysis of phase I, phase II, and phase III clinical trials, including cross-over studies, bioequivalence studies, and community intervention trials. Students critiqued study protocols and published studies, planned clinical trials, and analyzed data from them. Students also developed a protocol for a clinical trial within their area of interest. Department of Epidemiology and Public Health, University of Miami School of Medicine, 1999-2004.

Design of Clinical Trials. Developed and taught a one-credit short course for graduate students in biostatistics. Students learned statistical methods and computer software for planning clinical trials. The course covered the design of phase III clinical trials, cross-over studies, bioequivalence studies, and community intervention trials. Students critiqued study protocols and they wrote a statistical section for a clinical trial of their choice. Department of Biostatistics, University of Pittsburgh Graduate School of Public Health, June 1998.

Planning Biomedical Studies. Developed and taught a three-credit course for graduate students in epidemiology and biostatistics. Students learned to apply statistical methods and use computer software for planning clinical trials (parallel groups, cross-over, community intervention, bioequivalence), cohort studies, case-control studies, sample surveys, and cross-sectional studies. Previously written grant proposals and problems developed by the Instructor served as case studies in the course. Students worked as members of teams in planning studies, and articulated through written and oral presentations, the statistical issues involved in study design and analysis. Students wrote statistical sections of study proposals to learn how to present the design of a study, its major scientific objectives, and the proposed analysis of its data. Department of Biostatistics, University of Pittsburgh Graduate School of Public Health, 1997.

Clinical Epidemiology and Biostatistics. Planned and organized this first-year medical student course involving over 140 medical students and 80 faculty as part of the new curriculum at the University of Pittsburgh School of Medicine. Served as Course Director, lectured on Biostatistics, conducted reviews for all exams, and wrote all examinations. University of Pittsburgh School of Medicine, 1992-1997.

Case-Control Studies. Invited lecturer on the analysis of case-control studies. Department of Biostatistics, University of Pittsburgh Graduate School of Public Health, 1992-1997.

Clinical Epidemiology and Biostatistics Prematriculation Course. Course Director and lecturer in epidemiology and biostatistics for this prematriculation course for medical students. University of Pittsburgh School of Medicine, 1993-1997.

Preventive Medicine. Led small-group discussions on the design, interpretation and analysis of epidemiologic studies in this second-year medical-student course. F. Edward Hebert School of Medicine, Uniformed Services University of the Health Sciences, 1983-1986.

Epidemiology and Biostatistics. Lectured on probability and survival analysis, wrote exams, and advised students in this first-year medical-student course. F. Edward Hebert School of Medicine, Uniformed Services University of the Health Sciences, 1988-1992.

Microcomputer Applications. Organized and team-taught this one-quarter graduate student course. F. Edward Hebert School of Medicine, Uniformed Services University of the Health Sciences, 1983-1992.

Service for University of Pittsburgh Cancer Institute (2004 – 2009)

Standing Committees

Cancer Informatics Services Advisory Committee, 2007 - 2009

Clinical Research Oversight Committee, 2004 - 2009

Clinical Research Committee, 2005 - 2009

Clinical Research Services Task Force, 2005 - 2006

Data and Safety Monitoring Committee, 2004 - 2007

Independent Data and Safety Monitoring Committee, 2004 - 2009

Protocol Review Committee B, 2004 - 2009

Service for University of Pittsburgh Medical Center (2008 – 2012)

Institutional Data and Safety Monitoring Board

Subcommittee for Study of MUC1 Peptide-MPL Adjuvant in Subjects with Advanced Colorectal Adenomas, 2008 - 2012.

Service for University of Miami (1997 – 2004)

Standing Committees

Executive Committee, Sylvester Comprehensive Cancer Center, 1997 - 2004

Scientific Steering Committee, Sylvester Comprehensive Cancer Center, 1997 - 2004

Protocol Review Committee, Sylvester Comprehensive Cancer Center, 1997 - 2004

Data and Safety Monitoring Committee, Sylvester Comprehensive Cancer Center, 2003 - 2004
 Audit Committee, Sylvester Comprehensive Cancer Center, 2002 - 2003
 Teaching Executive Policy Committee, Department of Epidemiology and Public Health, 1998 - 2001
 Research Committee, Department of Epidemiology and Public Health, 2000

Ad Hoc Committees

Research Committee, Department of Epidemiology and Public Health, 1998
 Search Committee (for leader of a new University of Miami Center for Research Design and Clinical Outcomes), University of Miami School of Medicine, 2003

Service for University of Pittsburgh (1992 – 1997)

Standing Committees

Medical Student Promotions 1994 - 1997

Ad Hoc Committees

Fact-Finding Committee for the Performance Review of George M. Bernier, Jr., M.D., Dean of the School of Medicine, 1994

Advisory Committee on the Management of the Biostatistical Center of NSABP, 1994

Search Committee for Director, NSABP Biostatistical Center (Chair), 1994

Appointment Committee for Professor of Biostatistics (GSPH), 1995

Prematriculation Program Planning Committee, 1995

MD/MPH Steering Committee, 1995-1997

Promotion and Tenure Committees

Thomas E. Rudy (Medicine), 1994

Joseph P. Costantino (Biostatistics), 1995

Michael E. Thase (Psychiatry), 1995

Carol J. Coffee (Biochemistry), 1995