#### CURRICULUM VITAE Jennifer Clark Nelson

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#### **1. Biographical Information**

Jennifer Clark Nelson, PhD Director of Biostatistics and Senior Investigator Biostatistics Unit Kaiser Permanente Washington Health Research Institute (formerly Group Health Research Institute) 1730 Minor Avenue, Suite 1600 Seattle, WA 98101-1448 Phone: (206) 287-2004 Fax: (206) 287-2871 Email: Jen.Nelson@kp.org

#### 2. Education

B.A. (*summa cum laude*), Mathematics and Accounting, Luther College, Decorah, IA, 1994 M.S., Biostatistics, University of Washington, Seattle, WA, 1996 Ph.D., Biostatistics, University of Washington, Seattle, WA, 1999 (<u>Advisor</u>: Dr. Margaret Pepe)

#### 3. Licensure

Not applicable

#### 4. Professional Positions

1994-1997	Pre-doctoral Research Assistant
	Group Health Research Institute, Seattle, WA
1997-1999	Pre-doctoral Research Assistant
	Biostatistics Division, Fred Hutchinson Cancer Research Center, Seattle, WA
1999-2003	Research Scientist & Deputy Director, Multi-Ethnic Study of Atherosclerosis
	Department of Biostatistics, University of Washington, Seattle, WA
2003-present	Scientific Investigator (Assistant 2003-2009, Associate 2009-2014, Full 2014+)
	Biostatistics Division, Kaiser Permanente Washington Health Research
	Institute, Seattle, WA
2004-present	Affiliate Professor (Assistant 2004-2010, Associate 2011-2015, Full 2016+)
	Department of Biostatistics, University of Washington, Seattle, WA
2014-present	Director of Biostatistics
	Biostatistics Division, Kaiser Permanente Washington Health Research
	Institute, Seattle, WA

#### 5. Honors, Awards, and Scholarships

1993-1994 CoSIDA GTE Academic All-American, Volleyball Luther College, Decorah, IA

1994	National Collegiate Athletic Association (NCAA) Postgraduate Scholar
1994	Pi Mu Epsilon National Mathematics Honor Society
1994	Phi Beta Kappa National Honor Society
1994-1996	Achievement Rewards for College Scientists (ARCS) Fellowship
	University of Washington, Seattle, WA
1994-1999	National Institutes of Health Predoctoral Trainee in Cardiovascular Research
1999	Outstanding Student Award
	Department of Biostatistics, University of Washington, Seattle, WA
2009	Margarette Kolczak Award for outstanding contributions in vaccine statistics Centers for Disease Control & Prevention (CDC), Atlanta, GA
2012	Best poster, Databases Special Interest Group
	International Conference on Pharmacoepidemiology, Barcelona, Spain
2013	Paper selected among the 2013 Articles of the Year
	American Journal of Epidemiology and the Society for Epidemiologic Research
2015	Best reviewer, Pharmacoepidemiology and Drug Safety
2019	Distinguished Alumni Service Award
	Luther College, Decorah, IA
2020	Fellow, American Statistical Association (ASA)

## 6. Other Professional Activities

# Statistical Consultancies

1995	Cancer Center, University of Washington Medical Center, Seattle, WA
2003-2004	Department Family and Child Nursing, University of Washington, Seattle, WA
2003-2006	Divisions of Epidemiology and Medicine, Columbia University, New York, NY
2009	Global Clinical Safety & Pharmacovigilance, GlaxoSmithKline, Research
	Triangle Park, NC

## Memberships

Member: Executive, Ultrasound, and Computed Tomography Committees for NHLBI's Multi-Ethnic Study of Atherosclerosis Department of Biostatistics, University of Washington, Seattle, WA
Member, The American Statistical Association (ASA)
Member, The International Biometric Society (WNAR)
Member, Methodology Committee, Vaccine Safety Datalink collaboration,
Centers for Disease Control and Prevention (CDC)
Member, Executive Committee, ASA's Section in Epidemiology
Member, Affiliate Faculty Appointments Committee, Department of Biostatistics University of Washington, Seattle, WA
Member, Vaccine Safety Datalink Annual Meeting Planning Committee
Member, Scientific Policy Committee, Group Health Research Institute
Member, Strategic Planning Committee, Group Health Research Institute Member, International Biometric Society Regional Advisory Board (WNAR) Invited member, Vaccines Subcommittee, International Society for Clinical

	Biostatistics (ISCB)
2013-2016	Invited member, Methods Scientific Advisory Committee, Reagan-Udall
	Foundation's Innovation in Medical Evidence Development and Surveillance
	(IMEDS) Program for the Food and Drug Administration (FDA)
2018	Invited panelist, Improving the efficiency of outcome validation in the Sentinel
	System, Duke-Margolis Center for Health Policy, Washington DC, May 17, 2018
2018	Invited panelist, Signal Detection Capabilities in the Sentinel System, Duke-
	Margolis Center for Health Policy, Bethesda MD, December 3, 2018
2018-2021	Invited member, Data Monitoring Committee, HEPLISAV-B Vaccine Post
	Marketing Surveillance Study, Southern California Permanente Medical Group
2019-2020	Invited member, Strategic Plan Steering Committee, School of Public Health,
	University of Washington
2019-present	Executive Committee, FDA Sentinel Initiative Innovation Center
2019-present	Invited member, Advisory Board, Sentinel Site Readiness for Maternal
	Immunization Active Safety Surveillance in Low & Middle Income Countries, The
	Bill & Melinda Gates Foundation
2020-4/2021	Invited member, mRNA-1273 (COVID-19 vaccine candidate) External Safety
	Advisory Board, Moderna's COVID-19 vaccine program
5/2021-2023	Invited member, Advisory Committee on Immunization Practices (ACIP)
	COVID-19 Vaccine Safety Technical (VaST) Subgroup, CDC
2020-2022	Council of Sections Representative, ASA Section on Statistics in Epidemiology
2022	Invited member, ASA Council of Sections Governing Board Nominations
	Committee
2021-present	Member, International Biometric Society Regional Advisory Board (WNAR)
2023-present	Invited member, Advisory Committee on Immunization Practices (ACIP)
	COVID-19 Vaccines Working group, CDC, Atlanta GA
2023-2024	Member, Steering Committee for the 7 <sup>th</sup> Seattle Symposium in Biostatistics

## Leadership

1999-2003 2006-2007	Chair, Quality Control Committee, Multi-Ethnic Study of Atherosclerosis, NHLBI Chair, Affiliate Faculty Appointments Committee, Department of Biostatistics, University of Washington
2006-2008	Program Chair, Joint Statistical Meetings, ASA's Section in Epidemiology (chair- elect 2006, chair 2007, past chair 2008)
2008-2014	Chair, Methodology Committee, CDC's Vaccine Safety Datalink collaboration
2009-2019	Co-Lead, Methods Core, FDA's Sentinel Initiative Coordinating Center
2011-2013	Secretary, Vaccines Subcommittee, ISCB
2011	Co-Organizer, Vaccines Mini-Symposium at 32nd ISCB, Ottawa, Canada
2012	Co-Organizer, Vaccines Mini-Symposium at 33rd ISCB, Bergen, Norway
2013	Co-Organizer, Vaccines Mini-Symposium at 34th ISCB, Munich, Germany
2013-2014	Co-Chair, Vaccines Subcommittee, ISCB
2014	Co-Founder & Moderator, 1 <sup>st</sup> Seattle Symposium on Health Care Data Analytics: Confronting statistical challenges of using electronic health record data to conduct health research, September 28-30, Seattle WA
2015	Invited Moderator, America's Health Insurance Plans (AHIP) Roundtable: From Personalized Medicine to Population Health – Maximizing the Value of Data, December 3, Washington D.C.
2016	Co-Organizer, 2 <sup>nd</sup> Seattle Symposium on Health Care Data Analytics: Learning from electronic data to advance health and health care, October 23-25, Seattle WA.

2016	Organizer, WNAR-invited session on "Statistical methods to improve drug and
	vaccine safety surveillance using big health care data," XXVIIIth International
	Biometric Conference (IBC), July 10-15, Victoria B.C.
2017	Invited participant, Roundtable on "Integrating patient-reported health data and
	electronic health records data for pragmatic health research," Hosted by Duke
	Clinical Research Institute and the NIH, September 14, Bethesda MD
2018	Organizer, Invited session on "Improving the use of propensity score methods in
	large health care databases with rare outcomes," ASA's International
	Conference on Health Policy Statistics, January 10-12, Charleston SC
2018	Mentor, ASA's Statistics in Epidemiology Section Mentoring Program
2018-present	Associate Editor, Vaccine

#### Journal referee

Journal of Computational and Graphical Statistics, Statistics in Medicine, American Journal of Epidemiology, Epidemiology, Journal of Clinical Epidemiology, Pharmacoepidemiology and Drug Safety, Circulation, Vaccine, American Journal of Preventive Medicine, Journal of Infectious Diseases, Archives of Pediatrics & Adolescent Medicine, BMC Medical Research Methodology

#### Ad hoc reviewer

2014	Meeting abstracts, International Conference on Pharmacoepidemiology and
	Therapeutic Risk Management (ICPE)
2012	Analysis plan, Developing and evaluating methods for record linkage and
	reducing bias in patient registries, Agency for Healthcare Research and Quality
2017	Methodological report, Causal Inference for Effectiveness Research in Using
	Secondary Data, Patient Centered Outcomes Research Institute (PCORI)
2017	Short course proposal, Statistical Analysis of Large Administrative Health
	Databases, Banti International Research Station (BIRS)

## 7. Bibliography

\*Denotes mentored work of student

#### a) Peer-reviewed research articles

- 1. McBride CM, Curry SJ, Grothaus LC, **Nelson JC**, Lando HL and Pirie PL. Partner smoking status and pregnant smoker's perceptions of support for and likelihood of smoking cessation. *Health Psychol*. 1998;17:63-69.
- Hellerstedt WL, Pirie PL, Lando HL, Curry SJ, McBride CM, Grothaus LC, and Nelson JC. Differences in preconceptional and prenatal behaviors in women with intended and unintended pregnancies. *Am J Public Health*. 1998;88(4):663-666.
- McBride CM, Curry SJ, Lando HL, Pirie PL, Grothaus LC, and Nelson JC. Prevention of relapse in women who quit smoking during pregnancy. *Am J Pub Hlth*. 1999;89(5):706-711.
- 4. Ludman EJ, McBride CM, **Nelson JC**, Curry SJ, Grothaus LC, Lando HL, and Pirie PL. Stress, depressive symptoms, and smoking cessation among pregnant women. *Health Psychol.* 2000;19(1):21-27.
- 5. **Nelson JC**, Pepe MS. Statistical description of interrater variability in ordinal ratings. *Stat Methods Med Res.* 2000;9(5):475-496.

- Rautaharju PM, Nelson JC, Kronmal RA, Zhang Z, Robbins J, Gottdiener J, Furberg CD, Manolio T, and Fried L. Usefulness of T-axis deviation as an independent risk indicator for incident cardiac events in older men and women free from coronary heart disease (the Cardiovascular Health Study). Am J Cardiol. 2001;88(2):118-123.
- 7. Yanez ND III, Kronmal RA, **Nelson JC**, Alonzo TA. Analyzing change in clinical trials using quasi-likelihood. *J Applied Stat.* 2002;29(8):1135-1145.
- Bild DE, Bluemke DA, Burke GL, Detrano R, Diez Roux AV, Folsom AR, Greenland P, Jacobs Jr. DR, Kronmal RA, Liu K, **Nelson JC**, O'leary D, Saad MF, Shea S, Szklo M, Tracy RP. The Multi-Ethnic Study of Atherosclerosis (MESA): Objectives and Design. *Am J Epidemiol*. 2002;156(9):871-881.
- Robbins J, Nelson JC, Rautaharju PM, and Gottdiener J. The association between the length of the QT interval and mortality in the Cardiovascular Health Study. *Am J Med.* 2003;115(9):689–694.
- Carr JJ, Nelson JC, Wong ND, MCNitt-Gray M, Arad Y, Jacobs DR Jr, Sidney S, Bild DE, Williams OD, Detrano RC. Calcified coronary artery plaque measurement with cardiac CT in population-based studies: standardized protocol of the Multi-Ethnic Study of Atherosclerosis (MESA) and Coronary Artery Risk Development in Young Adults (CARDIA). *Radiology*. 2005;234(1):35-43.
- Nelson JC, Kronmal RA, Carr JJ, McNitt-Gray MF, Wong ND, Loria C, Goldin JG, Williams OD, Detrano R. Measuring coronary calcium on CT images adjusted for attenuation differences. *Radiology*. 2005; 235(2): 403-414.
- Lydon-Rochelle MT, Holt VL, Cardenas V, Nelson JC, Easterling TR, Gardella C, Callaghan WM. The reporting of pre-existing maternal medical conditions and complications of pregnancy on birth certificates and in hospital discharge data. *Am J Obstet Gynecol.* 2005;193(1):125-134.
- Jackson LA, Neuzil KM, Whitney CG, Starkovich P, Dunstan M, Yu O, Nelson JC, Feikin DR, Shay DK, Baggs J, Carste B, Nahm MH, Carlone G. Safety of varying dosages of 7-valent pneumococcal protein conjugate vaccine in seniors previously vaccinated with 23-valent pneumococcal polysaccharide vaccine. *Vaccine*. 2005;23(28):3697–3703.
- 14. Detrano RC, Anderson M, **Nelson JC**, Wong ND, Carr JJ, McNitt-Gray M, Bild DE. Coronary calcium measurements: effect of CT scanner type and calcium measure on rescan reproducibility--MESA study. *Radiology*. 2005;236: 477-484.
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- Jackson LA, Nelson JC, Whitney CG, Neuzil KM, Benson P, Malais D, Baggs J, Mullooly J, Black S, Shay DK. Assessment of the safety of a third dose of pneumococcal polysaccharide vaccination in the Vaccine Safety Datalink population. *Vaccine*. 2006;24(2): 151-156.
- 18. Rautaharju PM, Ge S, **Nelson JC**, Larsen EKM, Psaty BM, Furberg CD, Zhang Z, Robbins J, Gottdiener JS, Chaves PHM. Comparison of mortality risk for electrocardiographic abnormalities in men and women with and without coronary heart disease (from the Cardiovascular Health Study). *Am J Cardiol*. 2006;97:309-315.
- 19. Jackson LA, Dunstan M, Starkovich P, Dunn J, Yu O, **Nelson JC,** Rees T, Zavitkovsky A. Prophylaxis with acetaminophen or ibuprofen for prevention of local reactions to the fifth DTaP vaccination: a randomized, controlled trial. *Pediatrics*. 2006;117: 620-625.

- 20. Jackson LA, Jackson M, **Nelson JC** Neuzil KM, Weiss NS. Evidence of bias in estimates of influenza vaccine effectiveness in seniors. *Int J Epidemiol*. 2006;35: 337-344.
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- 35. Jackson LA, Yu O, Belongia EA, Hambidge SJ, **Nelson JC**, Baxter R, Naleway A, Gay C, Nordin J, Baggs J, Iskander J. Frequency of medically attended adverse events following

tetanus and diphtheria toxoid vaccine in adolescents and young adults: a Vaccine Safety Datalink study. *BMC Infect Dis.* 2009;9:165.

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- 37. <sup>†</sup>Yu O, **Nelson JC**, Bounds L, Jackson LA. Classification algorithms to improve the accuracy of identifying patients hospitalized with community-acquired pneumonia using administrative data. *Epidemiol Infect.* 2011;139:1296-1306.
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- 46. Cook AJ, Wellman RD, Marsh T, Li L, Heckbert S, Heagerty P, Tiwari RC, **Nelson JC**. Statistical approaches to group sequential monitoring of post-marketing safety surveillance data: Current state of the art for use in the Mini-Sentinel surveillance project. *Pharmacoepidemiology and Drug Safety*. 2012;21 Suppl 1:72-81.
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Administration's Mini-Sentinel Pilot Program: Status and Direction. *Pharmacoepidemiology and Drug Safety.* 2012;21 Suppl 1:1-8.

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## b) Other peer-reviewed scholarly publications

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## c) Books and book chapters

Not applicable

## d) Other non-peer-reviewed scholarly publications

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## e) Submitted manuscripts

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- Shi X, Zhai Y, Yu X, Li X, Hazlehurst BL, Nyongesa DB, Sapp DS, Williamson BD, Carrell DS, Healy L, Cushing-Haugen KL, Wong J, Wang SV, Floyd JS, Shattuck K, McGown S, Alam S, Bright P, Hernández-Muñoz JJ, Li J, Ma Y, Stojanovic D, Raman SR, Davis SE, Cai T, Nelson JC, Heagerty PJ. Harmonizing Electronic Health Record Data Across FDA Sentinel Initiative Data Partners Using Privacy-Protecting Unsupervised Learning: Case Study and Lessons Learned
- Li K, Emerman I, Yu O, Cook AJ, Jackson LA, Fireman B, Nelson JC, Shi X. Using Double Negative Controls to Adjust for Healthy User Bias in a Recombinant Zoster Vaccine Safety Study
- Denoble AE, Vazquez-Benitez G, Sheth SS, Ackerman CM, DeSilva MB, Zhu J, Daley MF, Getahun D, Klein NP, Vesco KK, Irving SA, Nelson JC, Williams JTB, Hambidge SJ, Donahue JG, Weintraub ES, Kharbanda EO, Lipkind HS. COVID-19 Vaccination and Stillbirth in the Vaccine Safety Datalink: A Case-Control Study.

## 8. Patents and Other Intellectual Property

Not applicable

## 9. Funding History

## a) Funded projects

- 1. Multiple Principal investigator (0.10 FTE): Sentinel Innovation Center, 2019-2023. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct costs: \$249,935.
- 2. Co-Investigator (0.25 FTE): Vaccine Safety Datalink Infrastructure Task Order, 2017-2022. Funded by the CDC (Principal Investigator, Lisa Jackson, MD, MPH). Direct costs: \$2.3M.
- 3. Site Principal investigator (0.05 FTE): Enhancing Causal Inference in the Sentinel system: An Evaluation of Targeted Learning and Propensity Scores for Confounding Control in Drug Safety, 2020-2022. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct costs: \$21,692.
- Task Order Co-Principal Investigator (0.10 FTE): The Sentinel Operations Center Learning Phenotype Laboratory, Phase 3, 2021-2023. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct costs: \$424,991.
- Multiple Principal Investigator & Contact PI (0.30 FTE): Adult Changes in Thought (ACT) U19 Program. Funded by the National Institute on Aging (other Principal Investigators, Rita Mangione-Smith, MD; Paul Crane, MD; Andrea LaCroix PhD). Direct costs: \$55M.

## b) Completed projects

- Senior Statistician and Co-Investigator (0.25 FTE from 8/99-8/03): Cardiovascular Health Study Morbidity and Mortality Follow-up - Coordinating Center, 1/1/88-5/31/05. Funded by the National Heart Lung and Blood Institute (Principal Investigator, Richard Kronmal, PhD). Direct costs: \$18,576,105.
- Deputy Director and Co-Investigator (0.75 FTE 8/99-8/03): Subclinical Cardiovascular Disease Study – Coordinating Center (alternate name: Multi-Ethnic Study of Atherosclerosis, MESA), 1/15/99-8/14/09. Funded by the National Heart Lung and Blood Institute (Principal Investigator, Richard Kronmal, PhD). Direct costs: \$11,699,997.
- Co-Investigator (0.10 FTE): Impact of Introduction of Pneumococcal Conjugate Vaccine on Pneumonia in Adults, 10/1/2003-09/30/2005. Funded by the CDC (Principal Investigator, Lisa Jackson, MD, MPH). Direct costs: \$169,763.
- Principal Investigator (0.20 FTE): Review of Statistical Methods for Post-Marketing Medical Product Safety Surveillance, 9/19/2008-3/18/2009. Funded by the FDA. (Principal Investigator, Jennifer Nelson, PhD). Direct costs: \$98,000.
- Co-Investigator (0.10 FTE): Prospective Drug Safety Surveillance using Sequential Analytic Methods: Two Approaches for Confounding Adjustment, 8/1/09-12/31/09. Funded by Observational Medical Outcomes Partnership and the Foundation for the National Institutes of Health (Principal Investigator, Lingling Li, PhD; Harvard Medical School). Direct costs: \$27,269.
- Co-Investigator (0.05 FTE): Efforts to Develop the Sentinel Initiative (Protocol for Active Surveillance of Medical Product-Related Acute Myocardial Infarction task order), 4/1/2010-7/31/2011. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$14, 092.
- Co-Investigator (0.20 FTE): Efforts to Develop the Sentinel Initiative (Sequential Testing Methods Development task order), 4/1/2010-7/31/2011. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$177,642.
- Co-Investigator (0.05 FTE): Efforts to Develop the Sentinel Initiative (Case-Based Methods Development task order), 2/1/2010-2/28/2011. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School).
- Co-Investigator (0.20 FTE): Efforts to Develop the Sentinel Initiative (Causal Inference and Sequential testing Methods Development task order), 1/1/2011-12/31/2011. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$170,000.
- Consultant/Mentorship Advisory Committee (0.00 FTE): Pharmacoepidemiology in the elderly -- medications, pneumonia risk, and confounding. Career Development Award (9/15/2007-8/31/2013). Funded by the National Institute on Aging (Principal Investigator, Sascha Dublin, MD, PhD; Mentor, Eric Larson, MD, PhD). Direct costs: \$800,000.
- Co-Investigator and Methodology Chair (0.70 FTE): Vaccine Safety Datalink Project, 10/1/02-9/30/12. Funded by the CDC (Principal Investigator, Lisa Jackson, MD, MPH). Direct costs: \$13,011,994
- 12. Co-Investigator (0.20 FTE): Efforts to Develop the Sentinel Initiative (Application of new sequential testing methods task order), 6/1/2012-5/31/2013. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$231,062.
- 13. Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Two-phase sampling methods development task order), 9/1/2012-8/31/2013. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$148,157.

- Co-Investigator (0.05 FTE): Vaccine Hesitancy Intervention—Provider, 7/2011-7/2013. Funded by the Group Health Foundation, Gates Foundation (Principal Investigator, David Grossman MD). Direct Costs: \$799,871.
- Task Order Principal Investigator (0.20 FTE): Efforts to Develop the Sentinel Initiative (Improvements to Prospective Routine Observational Monitoring Program Tools--PROMPT), 2/1/2014-8/31/2015. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$493,089.
- Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Safety signaling follow-up methods task order), 5/1/2015-10/31/2015. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$8,038.
- Site Principal Investigator (0.05 FTE): Efforts to Develop the Sentinel Initiative (Joint IMEDS-Mini Sentinel methods task order), 9/30/2013-10/31/2014. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$33,381.
- Site Principal Investigator (0.05 FTE): Efforts to Develop the Sentinel Initiative (Protocol for active surveillance of rivaroxaban task order), 9/23/2013-3/15/2015. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$13,732.
- Site Principal Investigator and Methods Core Co-lead (0.25 FTE): Efforts to Develop the Sentinel Initiative (Mini-Sentinel Coordinating Center): 9/23/09-9/22/15. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct costs: \$1,143,180.
- Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Safety signaling methods for survival outcomes to control for confounding), 9/1/2013-1/31/2015. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$216,053.
- Site PI and Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Roadmap to evaluating the performance of Sentinel analytic modules using simulation experiments), 6/1/2015-12/31/2015. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$29,698.
- 22. Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Protocol for Selected Medications and Sudden Death), 10/22/2013-2/21/2016. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$334,947.
- Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Comparison of safety signaling methods for survival outcomes to control for confounding, Phase 2), 5/1/2015-11/30/2016. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$281,486.
- Site PI and Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Evaluating the performance of Mini-Sentinel analytic modules using simulation experiments), 12/1/2015-6/30/2016. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$87,769.
- Site PI and Co-Investigator (0.05 FTE): Efforts to Develop the Sentinel Initiative (FDA/Mini-Sentinel/IMEDS Sequential Surveillance White Paper), 4/2016-3/2017. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$150,000.
- Co-Investigator (0.03 FTE): Racial/ethnic disparities in alcohol outcomes and health services, 9/2015 - 8/2017. Funded by the National Institute on Alcohol Abuse and Alcoholism (Principal Investigator: Joseph Glass, PhD; 1R03AA023639-01A1). Direct annual costs: \$50,000.

- Co-Investigator (0.10 FTE): Oral Health 4 Life: Integrating Oral Health Promotion & Tobacco Quitline Counseling, 8/1/2014-6/30/2018. Funded by the National Institute of Dental and Craniofacial Research (Principal Investigator: Jennifer McClure, PhD; 1U01DE024462-01) Direct costs: \$1,692,537.
- Co-Investigator (0.05 FTE): Vaccine Therapy and Evaluation Unit (VTEU), 2007-2017. Funded by the National Institute of Allergy and Infectious Diseases (Principal Investigator: Lisa Jackson, MD, MPH; HHSN272200800004C). Direct Costs: \$19,180,401.
- 29. Site Principal Investigator (0.25 FTE): Coordinating Center for Opioids Post-Marketing Requirement Observational Study 1B, 9/1/16-1/31/19. Funded by the Campbell Alliance, Ltd (Principal Investigator, Mary Ann McBurnie, PhD; Kaiser Permanente Center for Health Research). Direct costs: \$2.35M.
- 30. Site Principal Investigator and Methods Core Co-Lead (0.10 FTE): The Sentinel Initiative Coordinating Center: 9/23/15-9/22/19. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct annual costs: ~\$65,000.
- 31. Site Principal investigator (0.05 FTE): Shingrix vaccine surveillance, 2018-2019. Funded by GlaxoSmithKline (Principal Investigator, Jeff Brown ScD). Direct costs: \$16,105.
- Co-Investigator (0.05 FTE): Influenza Vaccine Effectiveness Center, 2016-2021. Funded by the CDC (Principal Investigator: Michael Jackson, PhD; U01IP001037). Direct Costs: \$3,161,462.
- 33. Task Order Co-Principal Investigator (0.10 FTE): The Sentinel Operations Center Learning Phenotype Laboratory, Phase 1, 2018-2020. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct costs: \$424,991.
- 34. Task Order Co-Principal Investigator (0.10 FTE): The Sentinel Operations Center Learning Phenotype Laboratory, Phase 2: 2019-2021. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct costs: \$528,484.
- 35. Co-investigator (0.03 FTE): Adult Changes in Thought (ACT) U01 study. Funded by the National Institute on Aging (Principal Investigators, Eric Larson, MD and Paul Crane, MD). Direct costs: \$10.3M.

## c) Pending applications

Not applicable at this time.

## 10. Conferences and Symposiums

Like presentations grouped. \*Denotes invited presentation

- 1. **Nelson JC.** A new descriptive method for exploring interrater variability in ordinal ratings. International Biometric Society (WNAR) Annual Meeting, San Diego, CA, July 1998.
- 2. **Nelson JC** and Pepe MS. Describing interrater variability in ordinal ratings. International Biometric Society (ENAR) Annual Meeting, Atlanta, GA, March 1999.
- 3. \*Nelson JC and Pepe MS. A graphical methodology for describing interrater variability in ordinal assessments among many raters. Southern Methodist University, Dallas, TX, April 1999.
- 4. **Nelson JC**. Graphical description of interrater variability in ordinal data. Group Health Research Institute, Seattle, WA, June 2003.
- Nelson JC and Pepe MS. Modeling and Estimating Interrater Variability in Ordinal Assessments Among Many Raters. International Biometric Society (WNAR) Annual Meeting, Fairbanks, AK, June 2005.

- Nelson, JC, Whitney, CG, Yu, O, Jackson, ML, Scott, T, Bounds, L, Zavitkovsky A, Jackson, LA. Impact of the Introduction of Pneumococcal Conjugate Vaccine on Rates of Community Acquired Pneumonia. 5<sup>th</sup> International Symposium on Pneumococci and Pneumococcal Diseases, Alice Springs, Central Australia, April 2006.
- Nelson, JC, Jackson LA, Jackson ML, Weiss NS. Methodological issues and strategies to reduce bias in observational studies of influenza vaccination effectiveness in the elderly. Conference on Statistical Methods in Epidemiology and Observational Studies In Honor of Norman E. Breslow, Seattle, WA, August 2006.
- 8. **Nelson, JC**, Jackson ML, Weiss NS, Jackson LA. A method to assess bias in observational studies of influenza vaccination effectiveness in the elderly. Joint Statistical Meetings, Salt Lake City, UT July 2007.
- Bittner RCL, Nelson JC. Use of propensity score calibration to reduce unmeasured confounding bias. University of Washington Biostatistics Retreat, Bainbridge Island, WA. September 2007.
- 10. **Nelson JC**. Strategies to reduce bias in estimates of influenza vaccine effectiveness in observational studies. Seattle Influenza Meetings, Seattle, WA, March 2008.
- 11. Zhao S, Cook AJ, **Nelson JC**. Statistical performance of group sequential methods for evaluating vaccine and drug safety. Joint Statistical Meetings, Denver, CO Aug 2008.
- 12. Nelson JC. Performance of Group Sequential Methods for Active Post-Licensure Medical Product Safety Surveillance Using Observational Health Care Databases. Poster presentation and Databases Special Interest Group award-winner at 28th International Conference on Pharmacoepidemiology and Therapeutic Risk Management, Barcelona, Spain, August 23-26, 2012.
- Nelson JC, Cook AC, Zhao S. Extending group sequential methods to observational medical product safety surveillance. Eastern North American Region of the International Biometrics Society Meetings, San Antonio TX; March 18, 2009.
- 14. \*Nelson, JC. Design and analysis considerations for post-marketing vaccine safety surveillance studies. Pediatric Academic Societies Annual Meeting, Baltimore MD; May 2-5, 2009.
- \*Nelson, JC. Evaluation of existing methods for safety signal identification for the Sentinel Initiative. Food and Drug Administration CBER/CDER/CDRH Joint Rounds, Silver Spring MD; May 6, 2009.
- 16. \*Nelson JC. Evaluation of existing methods for safety signal identification for the Sentinel Initiative. 2nd Annual Sentinel Initiative Public Workshop hosted by the Engelberg Center for Health Care Reform at Brookings. Washington D.C.; January 11, 2010.
- 17. \*Nelson JC. Signal Detection Methods for Active Post-Licensure Safety Surveillance. Think Tank: Methods, Tools, and Scientific Operations for The Sentinel Network, Engelberg Center for Health Care Reform at Brookings (convened in collaboration with the Centers for Educations and Research on Therapeutics (CERTs); Washington D.C.; May 7, 2009.
- \*Nelson JC. Discussion of Statistical Methods for Drug Safety Surveillance Using Electronic Health Care Databases. Joint Statistical Meetings, Vancouver BC; August 1, 2010.
- 19. \*Nelson JC. Sequential methods for observational post-licensure medical product safety surveillance. Third International Workshop in Sequential Methodologies, Stanford University, Palo Alto, CA; June 13-15, 2011.
- 20. **Nelson JC**, Cook AC, Yu O, Zhao S, Jackson LA. Challenges in designing a sequentiallymonitored observational study of post-licensure vaccine safety. Western North American Region of the International Biometrics Society Meetings, Seattle WA; June 21, 2010.
- Nelson JC, Cook AC, Yu O, Zhao S, Jackson LA. Challenges in designing a sequentiallymonitored observational study of post-licensure vaccine safety. International Biometrics Society Meetings, Florianopolis, Santa Catarina, Brazil; December 10, 2010.

- 22. **Nelson JC**. Challenges in conducting sequentially monitored medical product safety studies using electronic health care utilization data. International Conference on Pharmacoepidemiology & Therapeutic Risk Management, Chicago IL; August 16, 2011.
- 23. \*Nelson JC. The Vaccine Safety Datalink's near real-time safety surveillance system and challenges in designing sequentially-monitored vaccine safety studies. International Workshop in Pharmacoepidemiology and Biostatistics sponsored by the University of Washington, Group Health Research Institute, Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences, and VA Seattle Medical Center; Seattle, WA; December 2-4, 2011.
- 24. \*Nelson JC. An overview of methodological challenges in the U.S. FDA and CDC postmarket active surveillance systems. The First International Workshop on Safety Surveillance of Post-market Chinese Medicine Injection. China Academy of Chinese Medical Sciences, Bejing, China; April 7-8, 2012.
- 25. \*Nelson JC. Challenges in the design and analysis of sequentially-monitored postmarket safety surveillance evaluations using electronic observational health care data. Presentation at the 33rd International Society for Clinical Biostatistics, Bergen, Norway, August 19-23, 2012
- 26. \*Nelson JC. Methodological challenges for sequential medical product safety surveillance using observational healthcare data. Department of Biostatistics and Epidemiology, Perelman School of Medicine, University of Pennsylvania. Philadelphia, PA. May 9, 2013.
- 27. \*Nelson JC and Cook AJ. Methodological challenges in conducting post-licensure drug and vaccine safety surveillance using large electronic healthcare databases. Biostatistics and Biomathematics Program, Public Health Sciences Division, Fred Hutchinson Cancer Research Center. Seattle, WA, January 29, 2014.
- 28. \*Nelson JC. Methodological challenges in conducting post-licensure drug and vaccine safety surveillance using large electronic healthcare databases. Department of Statistics, University of Washington. Seattle, WA, April 14, 2014.
- 29. \*Nelson JC. Challenges in using large electronic healthcare databases to conduct postlicensure drug and vaccine safety surveillance. Data Management Association of Puget Sound Spring 2014 Conference, Seattle, WA, May 14, 2014.
- \*Nelson JC. Methodological challenges in conducting post-licensure drug and vaccine safety surveillance using large electronic healthcare databases. DIA (Develop, Innovate, Advance)/FDA Statistics 2015 Forum, Bethesda, MD, April 20, 2015.
- \*Nelson JC. Statistical challenges in post-market drug and vaccine safety surveillance using electronic health records. Central European Network of the International Biometric Society's (CEN-IBS) Joint Conference on Biometrics & Biopharmaceutical Statistics, Vienna, Austria, August 28 – September 1, 2017.
- 32. \*Nelson JC, Schneeweiss S. Expert Workshop: Setting priorities for methods research and development for active medical product surveillance hosted by the Engelberg Center for Health Care Reform at Brookings. Washington D.C.; June 3, 2011.
- Nelson JC. Developing better evidence on medical product safety: FDA's Mini-Sentinel Program, Methodological Activities and Highlights. AcademyHealth Annual Research Meeting, Seattle WA; June 13, 2011.
- 34. \*Nelson JC. Exploring the use of validation sample methods to reduce confounding bias in health care database estimates of influenza vaccination effectiveness in seniors. 4th Comparative Effectiveness Research Symposium "From Efficacy to Effectiveness". Presentation at the AHRQ DEcIDE Methods Symposium. Rockville, MD. June 12-13, 2012.
- 35. \*Marsh T, Nelson JC. Validation sampling to reduce bias in healthcare database studies. 29<sup>th</sup> International Conference on Pharmacoepidemiology and Therapeutic Risk Management, Montreal, Canada, August 25-28, 2013.

- 36. \*Nelson JC. Expert Workshop: "Overcoming the Statistical Challenges to the Reuse of Data within the Mini-Sentinel Distributed Database" hosted by the Engelberg Center for Health Care Reform at Brookings. Washington D.C.; September 5, 2012.
- 37. \*Nelson JC and Madigan D. Collaborations supporting active surveillance research. Fifth Annual Sentinel Initiative Public Workshop hosted by the Engelberg Center for Health Care Reform at Brookings. Washington D.C.; January 31, 2013.
- 38. \*Nelson JC and Cook AJ. Overview of distributed data methods and analyses within the HMO Research Network. Patient Centered Outcomes Research Institute (PCORI) Workshop: Distributed Analysis in Healthcare Data Networks. Washington D.C.; December 4, 2014.
- \*Nelson JC. Group sequential methods for vaccine pharmacovigilance. Methods for evaluating vaccine effectiveness and safety satellite workshop. Sydney, Australia; October 28, 2014.
- 40. \***Nelson JC**. Overview of systems for active post-marketing medical product surveillance in the USA. Keynote address at the Vaccine safety seminar on active surveillance for adverse events following immunization, hosted by the National Centre for Immunisation Research & Surveillance, Sydney, Australia; October 29, 2014.
- 41. \***Nelson JC**. Using large healthcare databases in the USA to assess vaccine safety. Keynote address at the Vaccine safety seminar on active surveillance for adverse events following immunization, hosted by the National Centre for Immunisation Research & Surveillance, Sydney, Australia; October 29, 2014.
- 42. \*Nelson JC, Cook AJ, and Heagerty P. The role of health care data analytics in health policy decision-making. Invited Speaker Luncheon, Section on Health Policy Statistics, Joint Statistical Meetings, Seattle WA, August 13, 2015.
- 43. **Nelson JC**. Adapting group sequential methods to observational drug and vaccine safety surveillance studies that use large electronic healthcare databases. Joint Statistical Meetings, Seattle WA, August 13, 2015.
- 44. \*Nelson JC. Precision medicine and the role of big data. Roundtable: From personalized medicine to population health maximizing the value of data, America's Health Insurance Plans, Washington D.C., December 3, 2015.
- 45. \***Nelson JC.** Generating policy-relevant statistical evidence in sequentially monitored vaccine and drug safety evaluations using electronic health record data. Joint Statistical Meetings, Chicago, IL, August 4, 2016.
- 46. \***Nelson JC.** Connecting the data to the science: A biostatistician's role in advancing drug safety knowledge. 2<sup>nd</sup> Seattle Symposium in Health Care Data Analytics, Seattle WA, October 25, 2016.
- 47. \*Nelson JC. Timely quantification of policy-relevant vaccine and drug safety evidence: What can we achieve using electronic health care data networks? Conference on risk modeling, management, and mitigation in health sciences, Centre de recherches mathématiques, Université de Montréal, December 11-13, 2017
- 48. \*Nelson JC. Use of propensity score methods in multi-site safety data networks: current practice and challenges. ASA's International Conference on Health Policy Statistics, Charleston SC, January 10-12, 2018.
- \*Nelson JC. The role of electronic health record data in vaccine policy decisions. Clinical Trials Affinity Group (CTAG), Fred Hutchinson Cancer Research Center, Seattle WA, March 26, 2018.
- 50. \***Nelson JC.** Statistical considerations in multi-site vaccine safety evaluations. Stakeholder meeting on Maternal Interventions Vigilance Harmonization in Low & Middle income countries (Bill & Melinda Gates foundation), Amsterdam, The Netherlands, May 1-2, 2018.
- 51. \*Nelson JC. Real-world biostatistics: perspectives from an alum. University of Washington, Department of Biostatistics Colloquium, Seattle WA, November 8, 2018.

- 52. \*Nelson JC. Sequential surveillance in the Vaccine Safety Datalink: Interim analysis results for a recombinant Zoster vaccine. Advisory Committee on Immunization Practices, Zoster Working Group, February 11, 2019.
- 53. \*Nelson JC. How big data can lead to safer drugs and vaccines. World Vaccine Congress 2019, Washington DC, April 14-15, 2019.
- 54. \*Nelson JC. Challenges for randomized trial-based sequential methods in real-world settings. American College of Epidemiology Annual Meeting, Pasadena CA, September 9, 2019.
- 55. \***Nelson JC.** Sequential design and analysis considerations when using electronic health care data to rapidly quantify new vaccine safety evidence. 13<sup>th</sup> Vaccine Congress, Bangkok, Thailand, September 15-18, 2019.
- 56. \*Nelson JC. University of Washington biostatistics students and alums making an impact in drug and vaccine safety science. University of Washington, Department of Biostatistics Seminar (for prospective student visit days), Seattle WA, February 27, 2020.
- 57. \*Nelson JC. Precision health in the age of data science: Learning from observational data (invited panelist). Sixth Seattle Symposium in Biostatistics, University of Washington, Department of Biostatistics, Seattle WA, November 21-23, 2020.

## 11. Professionally-Related Community Service

Not applicable

## 12. Teaching History

#### a) Formal courses

Biostatistics 511: Medical Biometry I, Department of Biostatistics, University of Washington, Seattle, WA, Teaching Assistant, Summer 1996.

- Biostatistics 511: Medical Biometry I, Department of Biostatistics, University of Washington, Seattle, WA, Teaching Assistant, Summer 1997.
- Using Electronic Healthcare Data for Comparative Safety and Effectiveness Research, Summer Institute in Statistics for Clinical Research, Department of Biostatistics, University of Washington, Seattle, WA, Instructor, June 27, 2014.

#### b) Other teaching

- Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, May 17, 2010.
- Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, April 30, 2012.
- Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, April 21, 2014.
- Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, April 20, 2016.

Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, May 9, 2018.

Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, April 1, 2020.

Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, March 30, 2022.

#### c) Independent study

- 2006 Rachel Bittner, Department of Biostatistics, University of Washington, Seattle WA
- 2011 Kelly Stratton, Department of Biostatistics, University of Washington, Seattle WA
- 2020 Iris Emerman, Department of Biostatistics, University of Washington, Seattle WA

#### 13. Advising and Formal Mentoring

#### a) Master's theses, chair

2006-2007	Rachel Bittner, Chair Master's Thesis Committee
	Department of Biostatistics, University of Washington, Seattle WA
2011-2012	Kelly Stratton, Chair Master's Thesis Committee
	Department of Biostatistics, University of Washington, Seattle WA
2020-2021	Iris Emerman, Chair Master's Thesis Committee
	Department of Biostatistics, University of Washington, Seattle WA

#### b) Mentored scientists and postdocs

2004-2007	Sascha Dublin, Member of K-award Postdoctoral Fellowship Advisory Board Health Services Research & Development, VA Puget Sound, Seattle, WA
2000-2003	Melissa Anderson, Research Scientist Supervisor
	Department of Biostatistics, University of Washington, Seattle, WA
2001-2003	Do Peterson, Research Scientist Supervisor
	Department of Biostatistics, University of Washington, Seattle, WA
2003-2017	Onchee Yu, MS Collaborative Biostatistician Supervisor
	Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
	Seattle, WA
2009-2017	Laura Ichikawa, MS Collaborative Biostatistician Supervisor
	Biostatistics Unit, Kaiser Permanente Washington Health Research Institute, Seattle, WA
2009-2014	Do Peterson, MS Collaborative Biostatistician Supervisor
	Biostatistics Unit, Kaiser Permanente Washington Health Research Institute, Seattle, WA
2014-2018	Melissa Anderson, MS Collaborative Biostatistician Supervisor
	Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
2015-2020	Jennifer Bobb, PhD Investigator Biostatistician Supervisor
2013-2020	Biostatistics Unit, Kaiser Permanente Washington Health Research Institute, Seattle, WA

2015-2016	Fei Wan, PhD Investigator Biostatistician Supervisor Biostatistics Unit, Kaiser Permanente Washington Health Research Institute, Seattle, WA
2016-2020	Yates Coley, PhD Investigator Biostatistician Supervisor
	Biostatistics Unit, Kaiser Permanente Washington Health Research Institute, Seattle, WA
2018-2019	Roberta De Vito, PhD Postdoctoral Research Fellow, Princeton University,
	Princeton NJ (part of ASA's Statistics in Epidemiology Mentoring Program)
2018-2020	Eric Johnson, MS Collaborative Biostatistician Supervisor
	Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
	Seattle, WA
2019-present	Maricela Cruz, PhD Investigator Biostatistician Supervisor
	Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
	Seattle, WA
2019-present	Yu-Ru Su, PhD Investigator Biostatistician Supervisor
	Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
	Seattle, WA

## c) Master's and PhD committee in non-chair role

2004-2007	Michael Jackson, Member of Doctoral Dissertation Committee
	Department of Epidemiology, University of Washington, Seattle, WA
2017-2018	Katherine Tan, Reading Committee Member for Doctoral Dissertation
	Department of Biostatistics, University of Washington, Seattle, WA
2019-2022	Ernesto Ulloa, Reading Committee Member for Doctoral Dissertation
	Department of Biostatistics, University of Washington, Seattle, WA
2020-present	Lola Arakaki, Committee Member for Doctoral Dissertation
	Department of Epidemiology, University of Washington, Seattle, WA
2023-present	Graham Crawbuck, Committee Member for Doctoral Dissertation
	Department of Epidemiology, University of Washington, Seattle, WA

# d) Other mentoring

2005-2006	Kenneth Wu, Graduate Research Assistantship Supervisor Department of Biostatistics, University of Washington, Seattle, WA
2006-2007	Rachel Bittner, Graduate Research Assistantship Supervisor
	Department of Biostatistics, University of Washington, Seattle, WA
2007	Tanya Granston, Graduate Research Assistantship Supervisor
	Department of Biostatistics, University of Washington, Seattle, WA
2007-2010	Shanshan Zhao, Graduate Research Assistantship Supervisor
	Department of Biostatistics, University of Washington, Seattle, WA
2009-2011	Clara Dominguez-Islas, Graduate Research Assistantship Supervisor
	Department of Biostatistics, University of Washington, Seattle, WA
2011-2013	Kelly Stratton, Graduate Research Assistantship Supervisor
	Department of Biostatistics, University of Washington, Seattle, WA
2015-2022	Ernesto Ulloa, Graduate Research Assistantship Supervisor
	Department of Biostatistics, University of Washington, Seattle, WA
2017-2019	Chloe Krakauer, Graduate Research Assistantship Supervisor
	Department of Biostatistics, University of Washington, Seattle, WA

## e) Academic Advising

- 2008-2009 Karen Liu, Graduate Academic Advisor Department of Biostatistics, University of Washington, Seattle, WA
  2009-2013 Alison Kosel, Graduate Academic Advisor Department of Biostatistics, University of Washington, Seattle, WA
  2010-2014 Tracey Marsh, Graduate Academic Advisor
- Department of Biostatistics, University of Washington, Seattle, WA