TATSUKI KOYAMA

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EDUCATION

1998	Bachelor of Arts in Statistics University of California at Berkeley, Berkeley, CA
2000	Master of Arts in Statistics University of Pittsburgh, Pittsburgh, PA
2003	Doctor of Philosophy in Statistics University of Pittsburgh, Pittsburgh, PA

Doctoral Dissertation

Title	A framework for design of two-stage adaptive procedures
Advisors	Allan R. Sampson, Ph.D. (co-chair), Leon J. Gleser, Ph.D. (co-chair)

ACADEMIC APPOINTMENTS

2003 - 2011	Assistant Professor
2011 - 2013	Research Associate Professor
2013 - 2022	Associate Professor
2022 - present	Professor Department of Biostatistics, Vanderbilt University School of Medicine Vanderbilt Center for Quantitative Sciences

PROFESSIONAL ORGANIZATIONS

1998 - present	American Statistical Association Middle Tennessee Chapter Chapter representative (2005-2006), Treasurer (2006-2021)
2003 - present	The International Biometric Society
2006 - 2013	The Biometric Society of Japan

Professional Activities

A. Study Section Review

2008 NIH Study Section Review Panel. “Tumor stem cells in cancer biology, prevention, and therapy (P01)”

2009 NIH Study Section Review Panel. “Measures and determinants of smokeless tobacco use, prevention, and cessation (R01)”

2010 NIH Study Section Review Panel. “Drug discovery, chemoprevention, and targeted therapy (P01)”

2013 Cancer Research Program Review Panel. The Department of Defense Congressionally Directed Medical Research Programs.

2015 Florida Department of Health Biomedical Research Programs Review Panel.

2015 Focused Program Review Panel. The Department of Defense Congressionally Directed Medical Research Programs.

2016 ASCO Grants Selection Committee Young Investigators Award Review Panel.

2016 Cancer Research Program Review Panels. The Department of Defense Congressionally Directed Medical Research Programs.

2017 ASCO Grants Selection Committee. Career Development Award Review Panel.

2017 Focused Program Awards Review Panels. The Department of Defense Congressionally Directed Medical Research Programs.

2018 ASCO Grants Selection Committee. Career Development Award Review Panel.

2018 Florida Department of Health Biomedical Research Programs Review Panel.

2019 Cancer Research Program. The Department of Defense Congressionally Directed Medical Research Programs.

2020 Cancer Research Program Review Panel. The Department of Defense Congressionally Directed Medical Research Programs.

2022 Broad Agency Announcement (MRDC-BAA) within the Department of DefenseCongressionally Directed Medical Research Programs (CDMRP).

2023 Traumatic Brain Injury Psychological Health Research Program (TBIPHRP) for the Department of Defense Congressionally Directed Medical Research Programs (CDMRP).

2024 ZonMw programme Rational Pharmacotherapy 13th Open Call for the Dutch Organisation for knowledge and innovation in health, healthcare and well-being.

B. Journal Review

The Journal of Urology (Board of Statisticians)

PLOS ONE (Statistical Advisory Board)

Japanese Journal of Statistics and Data Science (Associate Editor)

Science: Translational Medicine

JAMA Oncology

Nature Cancer

Nature Communications

Statistics in Medicine

Cancer

Cancers

Cancer Prevention Research

Clinical Cancer Research

Journal of Clinical Oncology

PLOS Medicine

American Statistician

Biometrical Journal

Bioinformatics

Journal of Applied Statistics

Journal of Biopharmaceutical Statistics

Journal of Statistical Computation and Simulation

Journal of Statistical Planning and Inference

Kidney International

Journal of Nuclear Medicine

International Journal of Environmental Research and Public Health

Expert Opinion on Drug Safety

Environmental Research and Public Health

Journal of Biological Chemistry

Kidney Research and Clinical Practice

Cell Reports Medicine

Advances in Medical Science

Breast Cancer Research

C. Awards and Honors

1996	Phi Theta Kappa
1996	Dean's List, University of California at Berkeley
1998	W. Homan Scholarship. University of California at Berkeley
2001	Best Teaching Assistant Award. Department of Statistics, University of Pittsburgh
2002	Best Senior Graduate Student Award. Department of Statistics, University of Pittsburgh
2002 - 2003	Andrew Mellon Pre-doctoral Fellowship. University of Pittsburgh
2003	Outstanding Graduate Student Award. American Statistical Association, Pittsburgh Chapter
2014, 2017	The Patrick G. Arbogast Collaborative Publication Award, Department of Biostatistics, Vanderbilt University School of Medicine

D. Intramural Services

University of Pittsburgh

2000	Statistics Computer Lab Coordinator
2000 - 2002	Statistical Consultant, Center for Statistics

Vanderbilt University Medical Center

2003 - present	Director of Biostatistics Core, Vanderbilt Digestive Disease Research Center
2003 - 2017	Member, Ph.D. Search Committee, Department of Biostatistics
2007	Reviewer, Vanderbilt Committee for Internal Pre-review of Grant Application
2009 - present	Reviewer, Scientific Review Committee, Vanderbilt-Ingram Cancer Center
2009 - 2017	Organizer, Cancer Biostatistics Workshop [2009-2011], Center for Quantitative Sciences Workshop [2011 - 2017]
2010 - 2011	Co-chair, Adaptive Clinical Trials Working Group, Center for Quantitative Sciences / Cancer Biostatistics Center
2011 - present	Executive committee member, Center for Qualitative Sciences.
2014 - present	Member, Graduate Student Admission Committee, Department of Biostatistics
2017 - present	Member, Limited Submission Opportunity Review Committee, VUMC
2018 - present	Member, Resource Allocation Committee, Department of Biostatistics
2018 - 2021	Member, Staff Promotion Committee, Department of Biostatistics
2019 - present	Member, Faculty Search Committee, Department of Biostatistics

Teaching Activities

A. Teaching Positions

1998 - 2002	Teaching Fellow / Teaching Assistant, Department of Statistics, University of Pittsburgh
2000	Lecturer, Department of Statistics, University of Pittsburgh
2009 - 2017	Organizer, Cancer Biostatistics Workshop, Cancer Biostatistics Center, Vanderbilt-Ingram Cancer Center; CQS Workshop, Center for Quantitative Sciences, Vanderbilt University School of Medicine.

B. Graduate Course

2012 - 2020	BIOS 6321: Clinical Trials and Experimental Designs (3 credits). Developed the course.
2020 - present	PUBH 5502: Biostatistics I (MPH program, 3 credits). Substantially updated the course materials.

C. Extramural Lectures

Tutorial session

1. Adaptive and flexible designs in clinical trials. *The 2006 Japanese Joint Statistical Meetings*. Sendai, Japan. September 5, 2006 (3 hour tutorial).

Short courses

2. Adaptive and flexible designs in clinical trials. *Japan Clinical Research Division*, Lilly Research Laboratories Japan. Kobe, Japan. March 1, 2007 (2 hour course).

3. Adaptive designs in clinical trials. *Biostatistics Summer School*. Osaka University (Biostatistics and Epidemiology), Osaka, Japan. July 9-10, 2007 (9 hour course).

4. Advanced clinical trials in the US. *Biostatistics Executive Seminar 2011*. Statcom Co. Ltd., Tokyo, Japan. June 20, 2011 (2 hour course).

5. Frequentist adaptive design for phase II and III clinical trials. *Shionogi Research Seminar*. Shionogi & Co. Ltd., Osaka, Japan. August 24, 2012 (2 hour course).

6. Clinical trials. *Special Summer Course*. Osaka University (Biostatistics and Epidemiology), Osaka, Japan. July 6-10, 2015 (20 hour course).

7. Phase III clinical trials. *Medical Statistics*. Osaka University (Biostatistics and Epidemiology), Osaka, Japan. July 19-22, 2016 (9 hour course).

8. Selected topics in phase II and III clinical trials. Osaka City University (Medical Statistics), Osaka, Japan. (9 hour course)
   July 18-20, 2017
   August 16-17, 2018
   July 8-10, 2019
   January 11-14, 2021
   November 9-17, 2021

Invited lectures

9. Meta analysis, interim analysis and data safety monitoring boards. *Clinical Trials and Research*, Masters of Science in Clinical Investigation (MSCI) program, Meharry Medical College, Nashville, TN. November 9 and 23, 2010 (2.5 hour course).

10. Randomization in clinical trials. *Nashville Chapter, Society of Clinical Research Associates*. October 24, 2013.

11. Study design and power calculations. *Mouse Kidney Injury Workshop*. Vanderbilt University O'Brien Kidney Center. August 2022; August 2023.

D. Intramural Lectures

Short Courses

1. Biostatistics I. *Center for Quantitative Sciences Summer Institute*. Center for Quantitative Sciences. August 3-7, 2015; August 1-5, 2016; August 7-11, 2017; August 9-13, 2021. (15 hour lecture)

Invited Lectures

2. Introduction to statistics in R. *Seminar Series in Biostatistics*. Department of Biostatistics. 2004.
3. Probabilities and statistics in medicine. *Guest lecturer for Department of Preventive Medicines' required course*. 2004–2007.
4. Power and sample size: A practical point of view. *Guest lecture for MSCI course, Biostatistics I*. 2004.
5. Tools for formal statistical inference. *Statistical Thinking in Biomedical Research*. Department of Biostatistics. 2004.
6. How to reduce sample size and control type I error rate by implementing two-stage designs. *GCRC Research Skills Workshop Series*. January, 2005.
7. Problems with using Excel for statistics. *GCRC Research Skills Workshop Series*. May, 2005.
8. Statistical methods in biomarker discovery. *Clinical Proteomics*. Vanderbilt University School of Medicine. 2008–2009.
9. Adaptive phase II clinical trials: Rigorous statistics and flexible science. *2008 Cancer Biostatistics Workshop*. Cancer Biostatistics Center. April, 2008.
10. Statistical methods in biomarker discovery. *2009 Cancer Biostatistics Workshop*. Cancer Biostatistics Center. April, 2009.
11. Technical aspects of interim monitoring in clinical trials. *GCRC Research Skills Workshop Series*. July, 2009.
12. Principles of presenting data: A statistical point of view. *Guest lecture for a freshman seminar in the College of Engineering, "Visual Display of Quantitative Information".* November, 2009.
13. Some aspects of statistical methods for biomarker discovery. *Continuing Education for Masters Biostatisticians*. Department of Biostatistics. December, 2009.
14. Statistical methods for biomarker discovery. *Statistics and Methodology Core Training Seminar*. Vanderbilt Kennedy Center. January, 2010.
15. Interim monitoring in clinical trials. *GCRC Research Skills Workshop Series*. September, 2010.
16. Topics in probability and statistics. *Guest lecture for a freshman course in School for Science and Math at Vanderbilt*. September, 2010.
17. Rigorous statistics for simple experiments: Basic science from a statistician's point of view. *The Vanderbilt Digestive Disease Research Center Seminar Series*. September, 2010.
18. Clinical trial series, session II: Randomization. *GCRC Research Skills Workshop Series*. November, 2011.
19. Clinical trial series, session III: Interim analysis. *GCRC Research Skills Workshop Series*. December, 2011.

20. Randomization. *GCRC Research Skills Workshop Series*. August, 2012.
21. Flexible clinical trials. *GCRC Research Skills Workshop Series*. May, 2013.
22. Phase I clinical trials. *GCRC Research Skills Workshop Series*. November, 2013.
23. Randomization. *GCRC Research Skills Workshop Series*. November, 2013.
24. Clinical trials. *Introduction to Clinical and Translational Research*. January, 2015. (2 one-hour lectures)
25. Problems with using Excel for statistics. *GCRC Research Skills Workshop Series*. April, 2015.
26. Analytic challenges of pragmatic trials. *Two-hour lecture for V-POCKET seminar series*. February, 2015.
27. Phase I clinical trials. *GCRC Research Skills Workshop Series*. August, 2015.
28. Statistics for basic sciences. *DDRC Career Development Workshop*. 2015, 2016, 2018, 2020.
29. Statistics 101. *Radiation Oncology Research Group*. June, 2016.
30. Topics in regression analysis *GCRC Research Skills Workshop Series*. March, 2017
31. Phase I clinical trials. *Clinical Pharmacology Teaching Conferences*. April, 2017
32. Multiplicity in clinical trials. *GCRC Research Skills Workshop Series*. September, 2018
33. Phase II and III clinical trials. *Clinical Pharmacology Fellow Lecture*. January, 2020
34. Topics in regression analysis *GCRC Research Skills Workshop Series*. May, 2020
35. Topics in regression analysis: interaction vs subgroups; baseline adjustment vs difference. *VDDRC Academy of Investigators Workshop*. November, 2020
36. Dose-finding clinical trials in cancer. 3+3 and beyond (but not much). *Vanderbilt Center for Health Services Research Biostatistics Seminar*. November, 2020
37. Regression analysis: Interactions and subgroups and other topics. *Clinical Pharmacology Fellow Lecture*. April, 2021
38. Topics in regression analysis *GCRC Research Skills Workshop Series*. October, 2021
39. Randomization / Multiplicity control *Clinical Pharmacology Fellow Lecture*. November, 2021
40. Phase II clinical trials / Survival analysis *Journal club for Hematology/Oncology Fellows*. November, 2021.
41. Phase I clinical trials. *Clinical Pharmacology Teaching Conferences*. November, 2022
42. Analysis of variance, Regression analysis, Interaction and subgroups. *DDRC Academy of Investigators Program*. November, 2022.

43. Phase III clinical trials / Survival analysis. *Journal club for Hematology/Oncology Fellows*. November, 2022.
44. Phase 1/2 and Phase 2/3 Clinical Trials. *Clinical Pharmacology T32 Fellow Conference*.
45. Non-inferiority trials in oncology. *Vanderbilt Radiation Oncology Resident Research Retreat*.

E. Research Supervision

Department of Biostatistics, Vanderbilt University School of Medicine.

Mingsheng Guo, PhD. Bioinformatician I.

Sharon Phillips, MSPH. Assistant in Biostatistics.

Elizabeth Koehler, MS. Biostatistician III.

Pengcheng Lu, MS. Biostatistician III.

Zhiguo Zhao, MS. Biostatistician IV.

JoAnn Alvarez, MS. Biostatistician III.

Kang-Hsien Fan, MS. Biostatistician III.

Lan Cui, MS. Research Assistant I.

Liping Du, PhD. Bioinformatician III.

Li-Ching Huang, PhD. Staff Scientist.

Julius Kirui, MS. Intern.

Rachel J Baldwin, MS. Intern.

Corey J Horton, MS. Intern.

Huang Yi, MS. Biostatistician II.

Yufan Chen, MS. Biostatistician II.

Lili Sun, PhD. Senior Biostatistician.

Kevin Zhang, MS. Biostatistician.

Aaron Lee, MS. Senior Biostatistician.

F. Graduate Students

Department of Biostatistics, Vanderbilt University School of Medicine.

Emily N Peterson. MS thesis “Assessment of propensity score performance in small samples”. (August 2015)

Molly A Olson. MS thesis “A comparison of approaches for unplanned sample size changes in phase II clinical trials”. (May 2017)

Alese Halvorson. MS thesis “A statistical critique of normalization methods in basic science research”. (December 2019)

Justin Jacobs. MS thesis “A simulated exploration of alternatives to standard expansion cohorts in phase I trials”. (December 2022)

Publications and Presentations

A. Peer Reviewed Publication

1. Layman W and **Koyama T**. A clinical comparison of LED and halogen curing units. *J Clin Orthod*, 38(7):385–387, 2004. PMID: 15304953.

2. **Koyama T**, Sampson AR, and Gleser LJ. A calculus for design of two-stage adaptive procedure. *J Am Stat Assoc*, 100(469):197–203, 2005.

3. Rhodes M, Lautz T, Kavanaugh-Mchugh A, Manes B, Calder C, **Koyama T**, Liske M, Parra D, and Frangoul H. Pericardial effusion and cardiac tamponade in pediatric stem cell transplant recipients. *Bone Marrow Transplant*, 36(2):139–144, 2005. PMID: 15908968.

4. **Koyama T**, Sampson AR, and Gleser LJ. A framework for two-stage adaptive procedures to simultaneously test non-inferiority and superiority. *Stat Med*, 24(16):2439–2456, 2005. PMID: 15977285.

5. Schwartz DA, Connolley CD, **Koyama T**, Wise PE, and Herline AJ. Calcaneal ultrasound bone densitometry is not a useful tool to screen patients with inflammatory bowel disease at high risk for metabolic bone disease. *Inflamm Bowel Dis*, 11(8):749–754, 2005. PMID: 16043991.

6. **Koyama T** and Westfall PH. Decision-theoretic views on simultaneous testing of superiority and noninferiority. *J Biopharm Stat*, 15(6):943–955, 2005. PMID: 16279353.

7. Keates-Baleeiro J, Moore P, **Koyama T**, Manes B, Calder C, and Frangoul H. Incidence and outcome of idiopathic pneumonia syndrome in pediatric stem cell transplant recipients. *Bone Marrow Transplant*, 38(4):285–289, 2006. PMID: 16819436.

8. Jones E, **Koyama T**, Ho RH, Kuttesch J, Shankar S, Whitlock JA, Cartwright J, and Frangoul H. Safety and efficacy of a continuous infusion, patient-controlled antiemetic pump for children receiving emetogenic chemotherapy. *Pediatr Blood Cancer*, 48(3):330–332, 2007. PMID: 16304666.

9. Sepmeyer JA, Greer JP, **Koyama T**, and Zic JA. Open-label pilot study of combination therapy with rosiglitazone and bexarotene in the treatment of cutaneous T-cell lymphoma. *J Am Acad Dermatol*, 56(4):584–587, 2007. PMID: 17184879.

10. M'Koma AE, Blum DL, Norris JL, **Koyama T**, Billheimer D, Motley S, Ghiassi M, Ferdowsi N, Bhowmick I, Chang SS, Fowke JH, Caprioli RM, and Bhowmick NA. Detection of pre-neoplastic and neoplastic prostate disease by MALDI profiling of urine. *Biochem Biophys Res Commun*, 353(3):829–834, 2007. PMID: 17194448. PMCID: PMC2562600.

11. **Koyama T**. Flexible design of two-stage adaptive procedures for phase III clinical trials. *Contemp Clin Trials*, 28(4):500–513, 2007. PMID: 17307399.

12. **Koyama T** and Chen H. Proper inference from Simon's two-stage designs. *Stat Med*, 27(16):3145–3154, 2008. PMID: 17960777. PMCID: PMC6047527.

13. Stumph J, Vnencak-Jones CL, **Koyama T**, and Frangoul H. Comparison of peripheral blood and bone marrow samples for detection of post transplant mixed chimerism. *Bone Marrow Transplant*, 41(6):589–590, 2008. PMID: 18037938.

14. Branner CM, **Koyama T**, and Jensen GL. Racial and ethnic differences in pediatric obesity-prevention counseling: National prevalence of clinician practices. *Obesity (Silver Spring)*, 16(3):690–694, 2008. PMID: 18239563.

15. Dar AA, Zaika A, Piazuelo MB, Correa P, **Koyama T**, Belkhiri A, Washington K, Castells A, Pera M, and El-Rifai W. Frequent overexpression of Aurora Kinase A in upper gastrointestinal adenocarcinomas correlates with potent antiapoptotic functions. *Cancer*, 112(8):1688–1698, 2008. PMID: 18311783. PMCID: PMC4030394.

16. Kawaguchi M, Hager HA, Wada A, **Koyama T**, Chang MS, and Bader DM. Identification of a novel intracellular interaction domain essential for Bves function. *PLoS One*, 3(5):e2261, 2008. PMID: 18493308. PMCID: PMC2373926.

17. Edelblum KL, Washington MK, **Koyama T**, Robine S, Baccarini M, and Polk DB. Raf protects against colitis by promoting mouse colon epithelial cell survival through NF-κB. *Gastroenterology*, 135(2):539–551, 2008. PMID: 18598699. PMCID: PMC2640938.

18. Edelblum KL, Goettel JA, **Koyama T**, McElroy SJ, Yan F, and Polk DB. Tnfr1 promotes tumor necrosis factor-mediated mouse colon epithelial cell survival through RAF activation of NF-κB. *J Biol Chem*, 283(43):29485–29494, 2008. PMID: 18713739. PMCID: PMC2570867.

19. Li X, Placencio V, Iturregui JM, Uwamariya C, Sharif-Afshar AR, **Koyama T**, Hayward SW, and Bhowmick NA. Prostate tumor progression is mediated by a paracrine TGF-β/Wnt3a signaling axis. *Oncogene*, 27(56):7118–7130, 2008. PMID: 18724388. PMCID: PMC3222150.

20. Blum DL, **Koyama T**, M'Koma AE, Iturregui JM, Martinez-Ferrer M, Uwamariya C, Smith JA Jr, Clark PE, and Bhowmick NA. Chemokine markers predict biochemical recurrence of prostate cancer following prostatectomy. *Clin Cancer Res*, 14(23):7790–7797, 2008. PMID: 19047106. PMCID: PMC3050736.

21. Piro CC, Crossno CL, Collier A, Ho R, **Koyama T**, and Frangoul H. Initial vancomycin dosing in pediatric oncology and stem cell transplant patients. *J Pediatr Hematol Oncol*, 31(1):3–7, 2009. PMID: 19125078.

22. Weitkamp JH, Rudzinski E, **Koyama T**, Correa H, Matta P, Alberty B, and Polk DB. Ontogeny of FOXP3(+) regulatory T cells in the postnatal human small intestinal and large intestinal lamina propria. *Pediatr Dev Pathol*, 12(6):443–449, 2009. PMID: 19203136. PMCID: PMC2844857.

23. Frangoul H, **Koyama T**, and Domm J. Etanercept for treatment of idiopathic pneumonia syndrome after allogeneic hematopoietic stem cell transplantation. *Blood*, 113(12):2868, 2009. PMID: 19299655.

24. Pallavaram S, Dawant BM, **Koyama T**, Yu H, Neimat J, Konrad PE, and D'Haese PF. Validation of a fully automatic method for the routine selection of the anterior and posterior commissures in magnetic resonance images. *Stereotact Funct Neurosurg*, 87(3):148–154, 2009. PMID: 19321967. PMCID: PMC2835380.

25. Sisler IY, Koehler E, **Koyama T**, Domm JA, Ryan R, Levine JE, Pulsipher MA, Haut PR, Schultz KR, Taylor DS, and Frangoul HA. Impact of conditioning regimen in allogeneic hematopoetic stem cell transplantation for children with acute myelogenous leukemia beyond first complete remission: A pediatric blood and marrow transplant consortium (PBMTC) study. *Biol Blood Marrow Transplant*, 15(12):1620–1627, 2009. PMID: 19896086.

26. Love HD, Booton SE, Boone BE, Breyer JP, **Koyama T**, Revelo MP, Shappell SB, Smith JR, and Hayward SW. Androgen regulated genes in human prostate xenografts in mice: Relation to BPH and prostate cancer. *PLoS One*, 4(12):e8384, 2009. PMID: 20027305. PMCID: PMC2793011.

27. Masaki N, **Koyama T**, Yoshimura I, and Hamada C. Optimal two-stage designs allowing flexibility in number of subjects for phase II clinical trials. *J Biopharm Stat*, 19(4):721–731, 2009. PMID: 20183436.

28. Rosen MJ, Moulton DE, **Koyama T**, Morgan WM 3rd, Morrow SE, Herline AJ, Muldoon RL, Wise PE, Polk DB, and Schwartz DA. Endoscopic ultrasound to guide the combined medical and surgical management of pediatric perianal Crohn's disease. *Inflamm Bowel Dis*, 16(3):461–468, 2010. PMID: 19637325. PMCID: PMC2871764.

29. Ware LB, **Koyama T**, Billheimer DD, Wu W, Bernard GR, Thompson BT, Brower RG, Standiford TJ, Martin TR, and Matthay MA. Prognostic and pathogenetic value of combining clinical and biochemical indices in patients with acute lung injury. *Chest*, 137(2):288–296, 2010. PMID: 19858233. PMCID: PMC2816641.

30. Fremont RD, **Koyama T**, Calfee CS, Wu W, Dossett LA, Bossert FR, Mitchell D, Wickersham N, Bernard GR, Matthay MA, May AK, and Ware LB. Acute lung injury in patients with traumatic injuries: Utility of a panel of biomarkers for diagnosis and pathogenesis. *J Trauma*, 68(5):1121–1127, 2010. PMID: 20038857. PMCID: PMC3347639.

31. Mukherjee K, Peng D, Brifkani Z, Belkhiri A, Pera M, **Koyama T**, Koehler EA, Revetta FL, Washington MK, and El-Rifai W. Dopamine and cAMP regulated phosphoprotein MW 32 kDa is overexpressed in early stages of gastric tumorigenesis. *Surgery*, 148(2):354–363, 2010. PMID: 20580047. PMCID: PMC2919779.

32. Simon SD, **Koyama T**, Cheng JS, and Mericle RS. Incidence of clipping and coiling procedures: Aneurysm treatment of medicare patients, 1996 - 200. *AANS Neurosurgeon*, 20(1):16–19, 2011.

33. Esbenshade AJ, Simmons JH, **Koyama T**, Koehler E, Whitlock JA, and Friedman DL. Body mass index and blood pressure changes over the course of treatment of pediatric acute lymphoblastic leukemia. *Pediatr Blood Cancer*, 56(3):372–378, 2011. PMID: 20860019. PMCID: PMC3713225.

34. Bastarache JA, **Koyama T**, Wickersham NE, Mitchell DB, Mernaugh RL, and Ware LB. Accuracy and reproducibility of a multiplex immunoassay platform: A validation study. *J Immunol Methods*, 367(1-2):33–39, 2011. PMID: 21277854. PMCID: PMC3108329.

35. O'Neal HR Jr, **Koyama T**, Koehler EA, Siew E, Curtis BR, Fremont RD, May AK, Bernard GR, and Ware LB. Prehospital statin and aspirin use and the prevalence of severe sepsis and acute lung injury/acute respiratory distress syndrome. *Crit Care Med*, 39(6):1343–1350, 2011. PMID: 21336116. PMCID: PMC3102130.

36. Williams K, **Koyama T**, Schulz D, Kaluza GL, Pautler RG, Weisbrodt N, and Conner ME. Use of fluoroscopy to study in vivo motility in mouse pups. *J Pediatr Gastroenterol Nutr*, 52(6):679–685, 2011. PMID: 21593642. PMCID: PMC3098421.

37. Deeley MA, Chen A, Datteri R, Noble JH, Cmelak AJ, Donnelly EF, Malcolm AW, Moretti L, Jaboin J, Niermann K, Yang ES, Yu DS, Yei F, **Koyama T**, Ding GX, and Dawant BM. Comparison of manual and automatic segmentation methods for brain structures in the presence of space-occupying lesions: A multi-expert study. *Phys Med Biol*, 56(14):4557–4577, 2011. PMID: 21725140. PMCID: PMC3153124.

38. Smith DS, Welch EB, Li X, Arlinghaus LR, Loveless ME, **Koyama T**, Gore JC, and Yankeelov TE. Quantitative effects of using compressed sensing in dynamic contrast enhanced MRI. *Phys Med Biol*, 56(15):4933–4946, 2011. PMID: 21772079. PMCID: PMC3192434.

39. Stabler S, **Koyama T**, Zhao Z, Martinez-Ferrer M, Allen RH, Luka Z, Loukachevitch LV, Clark PE, Wagner C, and Bhowmick NA. Serum methionine metabolites are risk factors for metastatic prostate cancer progression. *PLoS One*, 6(8):e22486, 2011. PMID: 21853037. PMCID: PMC3154200.

40. Ware LB, **Koyama T**, Billheimer D, Landeck M, Johnson E, Brady S, Bernard GR, and Matthay MA. Advancing donor management research: Design and implementation of a large, randomized, placebo-controlled trial. *Ann Intensive Care*, 1(1):20, 2011. PMID: 21906362. PMCID: PMC3224478.

41. **Koyama T**. Length of the Beatles' song. *Chance*, 25(1):30–33, 2012.

42. Korhonen K, Lovvorn HN 3rd, **Koyama T**, Koehler E, Calder C, Manes B, Evans M, Bruce K, Ho RH, Domm J, and Frangoul H. Incidence, risk factors, and outcome of pneumatosis intestinalis in pediatric stem cell transplant recipients. *Pediatr Blood Cancer*, 58(4):616–620, 2012. PMID: 21721114.

43. Martinez JA, **Koyama T**, Acra S, Mascarenhas MR, and Shulman RJ. Nutrition education for pediatric gastroenterology, hepatology, and nutrition fellows: Survey of NASPGHAN fellowship training programs. *J Pediatr Gastroenterol Nutr*, 55(2):131–135, 2012. PMID: 22343911. PMCID: PMC3395733.

44. Wu H, Chen Q, Ware LB, and **Koyama T**. A Bayesian approach for generalized linear models with explanatory biomarker measurement variables subject to detection limit - an application to acute lung injury. *J Appl Stat*, 39(8):1733–1747, 2012. PMID: 23049157. PMCID: PMC3463110.

45. Weitkamp JH, **Koyama T**, Rock MT, Correa H, Goettel JA, Matta P, Oswald-Richter K, Rosen MJ, Engelhardt BG, Moore DJ, and Polk DB. Necrotising enterocolitis is characterised by disrupted immune regulation and diminished mucosal regulatory (FOXP3)/effector (CD4, CD8) T cell ratios. *Gut*, 62(1):73–82, 2013. PMID: 22267598. PMCID: PMC3606820.

46. Fowke JH, Phillips S, **Koyama T**, Byerly S, Concepcion R, Motley SS, and Clark PE. Association between physical activity, lower urinary tract symptoms (LUTS) and prostate volume. *BJU Int*, 111(1):122–128, 2013. PMID: 22726636. PMCID: PMC3460041.

47. Resnick MJ, **Koyama T**, Fan KH, Albertsen PC, Goodman M, Hamilton AS, Hoffman RM, Potosky AL, Stanford JL, Stroup AM, Van Horn RL, and Penson DF. Long-term functional outcomes after treatment for localized prostate cancer. *N Engl J Med*, 368(5):436–445, 2013. PMID: 23363497. PMCID: PMC3742365.

48. Esbenshade AJ, Simmons JH, **Koyama T**, Lindell RB, and Friedman DL. Obesity and insulin resistance in pediatric acute lymphoblastic leukemia worsens during maintenance therapy. *Pediatr Blood Cancer*, 60(8):1287–1291, 2013. PMID: 23444342. PMCID: PMC3881979.

49. Edwards HD, Oakley F, **Koyama T**, and Hameed O. The impact of tumor size in breast needle biopsy material on final pathologic size and tumor stage: A detailed analysis of 222 consecutive cases. *Am J Surg Pathol*, 37(5):739–744, 2013. PMID: 23552386.

50. Hoffman RM, **Koyama T**, Fan KH, Albertsen PC, Barry MJ, Goodman M, Hamilton AS, Potosky AL, Stanford JL, Stroup AM, and Penson DF. Mortality after radical prostatectomy or external beam radiotherapy for localized prostate cancer. *J Natl Cancer Inst*, 105(10):711–718, 2013. PMID: 23615689. PMCID: PMC3653822.

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B. Extramural Seminars and Presentations

Session Chairs

1. Early phase clinical trials. *International Conference on Applied Statistics*, Tamkang University, Taipei, Taiwan. March 11-12, 2011.

2. Early phase combination trial. *Pacific Rim Cancer Biostatistics Workshop*, Kanazawa, Japan. October 12-13, 2017.

Invited presentations

1. A calculus for design of two-stage adaptive procedures. *Workshop on Adaptive Designs*. The Fields Institute, Toronto, Ontario, Canada. September 25-27, 2003.

2. A flexible method for design of two-stage adaptive procedures. *Meisei University*, Tokyo, Japan. December 15, 2003.

3. Two-stage adaptive procedures for simultaneously testing noninferiority and superiority. *American Statistical Association Middle Tennessee Chapter Meeting*. Nashville, TN. February 27, 2004.

4. Proper inference from Simon's two-stage designs. *Conference and Celebration for Leon Gleser and Tom Savits*. Department of Statistics, University of Pittsburgh. Pittsburgh, PA. May 5-6, 2006.
5. Applications of adaptive designs. *The 2006 Japanese Joint Statistical Meeting*. Sendai, Japan. September 7, 2006.
6. Applications of adaptive designs in phase II clinical trials. *Tokai Medical Association*, Isehara, Japan. September 11, 2006.
7. Miscellaneous topics in probability. *American Statistical Association Middle Tennessee Chapter Meeting*. Nashville, TN. October 27, 2006.
8. Inference from general adaptive designs. *Grants-in-Aid Conference on Applications of Multiple Decision Making in Clinical Drug Development*. Kobe, Japan. February 27-28, 2007.
9. Flexible designing of a two-stage adaptive procedures. *Targeted Designs for Clinical Trials*. Philadelphia, PA. July 19-20, 2007.
10. Bayesian statistics in academics in the United States. *Bayesian Statistics and the Future of Clinical Trials*. StatCom Company Fifth Anniversary Symposium, Tokyo, Japan. December 5, 2008.
11. Fundamentals of adaptive designs. *Forum for Antineoplastic Agent Development*. Japanese Foundation for Cancer Research. Tokyo, Japan. June 18, 2011.
12. The prudent statistician's guide to two-stage designs. *Public Health & Preventive Medicine Grand Rounds*. Knit Cancer Institute, Oregon Health Science & Science University. Portland, OR. December 19, 2013.
13. Statistical considerations for dose finding phase I clinical trials: a scientific reviewer's perspective. *Tokai Medical Association*, Isehara, Japan. July 10, 2014.
14. Rigorous statistics for basic and clinical sciences. *Division of Mathematical Sciences*, Osaka University, Osaka, Japan. July 16, 2014.
15. Statistics in phase I clinical trials. *University of Osaka*, Osaka, Japan. July 16, 2014.
16. Statistical considerations for dose finding phase I clinical trials. *Department of Statistics, National Cheng Kung University*, Tainan, Taiwan. September 9, 2014.
17. From 3+3 to mTPI: A Collaborative Biostatistician's Experience in a Comprehensive Cancer Center *Pacific Rim Cancer Biostatistics Workshop*, Kanazawa, Japan. October 12-13, 2017.
18. Multiplicity in clinical trial: FDA guidance and EMA guidelines. *2018 Association of Clinical and Translational Statistic. Annual Meeting*, Vancouver, Canada. July 29, 2018.
19. What we don't talk about when we talk about biostatistics: Challenges in data merging and treatment definition in a large-scale observational study *Department of Biostatistics, University of Louisville*, November, 2, 2018.

20. Very difficult non-biostatistical challenges that the team of biostatisticians faced in a large population-based cohort study in prostate cancer. *Hiroshima University Renal and Urology Research Seminar*, July 5, 2019.

21. Very difficult non-biostatistical challenges that the team of biostatisticians faced in a large population-based cohort study in prostate cancer. *Osaka City University Clinical Research Educational Seminar Series*, July 9, 2019.

22. Very difficult non-biostatistical challenges that the team of biostatisticians faced in a large population-based cohort study in prostate cancer. *Yokohama City University*, July 11, 2019.

23. Statistical considerations for designing a clinical trial. *Vanderbilt-Global Haploidentical Transplant Learning Collaborative Meeting*, Nashville, TN. September 9, 2019.

24. The Biostatistician's role in team science: a case study of collaborating on a large prostate cancer study. *Cancer Research Seminar Series*, The University of Tennessee Health Science Center, Memphis, TN. November 5, 2019.

Contributed Presentations

25. Flexible designing of two-stage adaptive procedures. *ENAR Spring Meeting*. Pittsburgh, PA. March 28-31, 2004.

26. Combinations of two-stage designs for testing multiple treatments in phase II cancer trials. *ENAR Spring Meeting*. Austin, TX. March 20 -23, 2005.

27. Significant design components in general two-stage adaptive procedures. *Joint Statistical Meeting*. Minneapolis, MI. August 7-11, 2005.

28. Pitfalls of simplistic normalization in basic science experiments. *Joint Statistical Meeting*. Vancouver, BC, Canada. July 29-August 5, 2010.

Contributed Posters

29. Two-stage procedures for simultaneously testing noninferiority and superiority. *Midwest Biopharmaceutical Statistical Workshop*. Muncie, IN. May 24-26, 2004.

C. Intramural Seminars and Presentations at Vanderbilt

1. Two-stage adaptive procedures for simultaneously testing noninferiority and superiority. *Biostatistics Seminar*. Department of Biostatistics. February, 2004.

2. General two-stage adaptive designs in phase III clinical trials. *Biostatistics Seminar*. Department of Biostatistics. February, 2005.

3. Proper inference from Simon's two-stage designs. *Biostatistics Seminar*. Department of Biostatistics. February, 2007.

4. Miscellaneous topics in probability and statistics. *Cancer Biostatistics Center Luncheon*. November, 2007

5. Bayesian biostatistics. *Cancer Biostatistics Center Luncheon*. March, 2008

6. *T*-test on fold changes. *Biostatistics Seminar*. Department of Biostatistics. June, 2010.

7. Non-analytical challenges faced by a team of biostatisticians when collaborating on a large cohort study in prostate cancer. *Biostatistics Seminar*. Department of Biostatistics. September, 2019.

Research Programs

The list includes some grants to which Dr. Koyama has contributed though the efforts have subsequently been transferred to other members of the Department of Biostatistics and Center for Quantitative Sciences.

5P50 CA090949 (Carbone) 9/1/2003 - 3/31/2012
NIH/NCI Role: Co-investigator
SPORE in Lung Cancer

The major goal of this project is to investigate the molecular features of tumors or tumor-host interactions to identify targets for intervention and improve outcomes for lung cancer patients.

5K24 CA080908 (Carbone) 9/1/2003 - 5/31/2005
NIH/NCI Role: Co-investigator
Molecular Therapeutics of Cancer

The major goal of this project is to enable the partnering of premiere institutions based in the Lung Cancer SPORE program to determine how the information derived from comprehensive molecular analyses can be used to improve patient care and outcomes.

R21 DK069527 (Bhowmick) 9/30/2003 - 8/31/2008
NIDDKD Role: Co-investigator
TGFβ Signaling in the Bladder Stroma

The major goal of this project is to explore the TGFβ-mediated signals in the stroma that mediate bladder estrogen and androgen responsiveness associated with bladder stromal hyperplasia.

2U01 CA099177 (Rothenberg) 12/01/2003 - 2/28/2009
NCI Role: Co-investigator
Vanderbilt Phase I Translational Research Program

The major goal of this project is to conduct early-phase, dose-ranging trials of new anticancer agents to characterize their toxicity, pharmacology, and effects on molecular targets.

5P01 CA077839 (DuBois) 5/1/2004 - 4/30/2010
NIH/NCI Role: Co-investigator
Mechanisms for Chemoprevention of Cancer

The major goal of this project is to determine the molecular mechanisms involved in the chemoprevention of cancer by NSAIDs.

5R01 CA108646 (Bhowmick) 8/1/2004 - 5/31/2010
NCI Role: Co-investigator
TGFβ Signals in Prostate Stromal-Epithelial Interactions

The major goal of this project is to specifically identify the TGFβ-mediated signals in the stroma that mediate prostate androgen responsiveness.

W81XWH-04-1-0867 (Hayward) 9/10/2004 - 9/14/2007
DOD Role: Co-investigator
An Myc-driven *in vivo* Model of Human Prostate Cancer

The major goal of this project is to develop a novel in vivo model of human prostate cancer based upon overexpression of the cMyc proto-oncogene.

AICR (Fowke) 2/1/2005 - 1/31/2007
American Institute for Cancer Research Role: Co-investigator
Effects of Brassica or Indole-3-Carbinol in Prostatectomy Patients with PSA Recurrence

The major goal of this project is to determine the effect of a diet rich in Brassica vegetables, or a non-nutrient diet supplement containing the Brassica-derived chemical believed to be biologically active, on PSA velocity.

U01 HL081332 (Ware) 8/12/2005 - 6/30/2010
NHLBI Role: Co-investigator
Biomarker Profiles in the Diagnosis/Prognosis of ARDS

The major goal of this project is to utilize a multi-disciplinary clinical proteomics approach to identify biomarkers for the diagnosis and prognosis of acute respiratory distress syndrome (ARDS).

5U01 CA114771 (Carbone) 9/30/2005 - 5/31/2011
NCI Role: Co-investigator
Molecular Signature of Lung Cancer (SPECS)

The major goal of this project is to evaluate the potential clinical usefulness of several molecular signatures already developed using a variety of molecular analysis technologies, including DNA, RNA, and protein-based technologies addressing both diagnostic and predictive signatures.

LAF Research Award (Matthews) 1/1/2006 - 12/31/2007
Lance Armstrong Foundation Role: Co-investigator
Exercise Intervention for Chemotherapy-Related Cognitive Dysfunction

The major goal of this project is to investigate the effects of exercise on chemotherapy-related cognitive dysfunction.

2R01 CA106176 (El-Rifai) 3/20/2006 - 6/30/2008
NCI Role: Co-investigator
Biomarkers in Barrett's Tumorigenesis

The major goal of this project is to discover novel diagnostic and/or prognostic molecular markers for Barrett's carcinomas.

2005 Research Reward (Fowke) 4/1/2006 - 3/31/2008
Prostate Cancer Foundation Role: Co-investigator
Glitazones and Prostate Cancer Risk in a Large Cohort of Men with Type II Diabetes

The major goal of this project is to determine the duration of Glitazone use, age at use, and most effective Glitazone associated with reduced prostate cancer risk.

P50 GM015431 (Oates) 7/3/2006 - 6/30/2011
NIH/NIGMS Role: Biostatistician
Research Center for Pharmacology and Drug Toxicology

The major goal of this project is to support research related to Eicosanoid biology and pharmacology.

R01 EB006193 (Dawant) 5/1/2007 - 2/28/2011
NIBIB Role: Co-investigator
Autosegmentation for Head and Neck Radiotherapy Planning

The major goal of this project is to develop, implement, and test the methodology required to automate the segmentation of structures in the treatment of patients with intracranial and head-and-neck cancers.

VUMC Discovery Grant (Koyama) 7/1/2007 - 6/30/2009
VUMC Role: Principal investigator
Proper Inference from a Simon's Design When The Sample Size is Changed

The major goal of this project is to develop a new analysis method that will compute a more accurate or proper p-value and confidence intervals for two-stage clinical trials.

5P30 DK058404 (Polk) 8/30/2007 - 5/31/2022
NIDDKD Role: Core leader
Molecular and Cellular Basis of Digestive Diseases

The major goal of this project is to investigate the molecular and cellular mechanisms responsible for digestive diseases.

5R01 HL088263 (Ware) 2/1/2008 - 1/31/2013
NHLBI Role: Co-investigator
Treatment of Pulmonary Edema in Organ Donors

The major goal of this project is to determine whether administration of an aerosolized beta-2 agonist in brain-dead organ donors will improve: 1) donor oxygenation by enhancing clearance of pulmonary edema and 2) donor lung procurement rates.

5R01 HD059253 (Malow) 4/1/2008 - 3/31/2010
NINDS Role: Co-investigator
Melatonin for Sleep in Children with Autism: Safety, Tolerability, and Dosing

The major goals of this project are to optimize the intervention strategy for administering supplemental melatonin in children with asd; characterize the pharmacokinetic profile of supplemental melatonin; and pilot a group of behavioral and parental stress scales in preparation for an rct.

5R01 CA077955 (Peek) 6/1/2008 - 3/31/2013
NCI Role: Co-investigator
H. Pylori Relationship to Digestive Diseases and Cancer

The major goal of this project is to define mechanisms through which H. Pylori induce epithelial responses with carcinogenic potential.

5R01 CA093999 (El-Rifai) 7/1/2008 - 4/30/2013
NCI Role: Co-investigator
Gene Amplification and Overexpression at 17q in Gastric Cancer

The major goal of this project is to investigate the prevalence of 17q alterations in gastric cancer and identify critical changes at this chromosomal region.

5P50 CA098131 (Arteaga) 9/11/2008 - 5/31/2013
NCI Role: Co-investigator
SPORE in Breast Cancer

The major goal of this project is to address basic, clinical, and population research questions in breast cancer.

5R01 CA095405 (Mahadevan-Jansen) 9/19/2008 - 7/31/2013
NCI Role: Co-investigator
Diagnosis of Cervical Precancers using Raman Spectroscopy

This project aims to assess the validity of the hypothesis that Raman spectroscopy can provide differential diagnosis of cervical precancers from inflammation, squamous metaplasia and normal areas of the cervix.

5P50 CA128323 (Gore) 9/22/2008 - 8/31/2013
NIH/NCI Role: Co-investigator
Vanderbilt *in vivo* Cellular and Molecular Imaging Center

The major goal of this project is to establish a new In Vivo Cellular and Molecular Imaging Center at Vanderbilt University which will be dedicated to highly innovative molecular imaging studies of cancer biology of direct relevance and translational potential to clinical cancer care.

5P01 CA116087 (Peek) 1/1/2009 - 8/31/2023
NCI Role: Co-investigator
H. Pylori-Induced Inflammation and Gastric Cancer

The major goal of this project is to delineate the molecular signaling events initiated by H. pylori: epithelial cell contact that regulates phenotypes related to gastric carcinogenesis.

DOD PC081246 (Bhowmick) 4/1/2009 - 3/31/2012
DOD Role: Co-investigator
Regulation and Function of Cytokines That Predict Prostate Cancer Metastasis

The major goal of this project is to identify the biologic role of specific chemokines shown to predict biochemical prostate cancer recurrence following prostatectomy.

5R01 DK081134 (Yan) 4/1/2009 - 3/31/2014
NIDDKD Role: Biostatistician
Probiotics-Derived Soluble Proteins Regulate Intestinal Inflammation

The major goals of this project are to investigate the relationships between p40 and intestinal cell survival, inflammation, and apoptosis.

5R01 CA131225 (El-Rifai) 6/1/2009 - 4/30/2014
NCI Role: Co-investigator
The Role of Aurora Kinase A in Upper Gastrointestinal Adenocarcinomas

The major goal of this project is to characterize the role of AURKA in GEC tumorigenesis to identify its biological, clinical, diagnostic, and prognostic value.

2R01 DK056008 (Polk) 8/1/2009 - 7/31/2014
NIDDK Role: Co-investigator
Cytokine Regulation of Intestinal Epithelial Restitution

The major goal of this project is to characterize the role of the TNFRs in regulating intestinal epithelial cells in health and after injury.

5R01 CA133738 (El-Rifai) 8/13/2009 - 7/31/2012
NCI Role: Co-investigator
The Role of T-Darpp in Upper Gastrointestinal Adenocracinomas

The major goals of this project are to determine the effects of t-Darpp expression on trastuzumab resistance, to investigate the mechanism(s) by which t-Darpp regulates apoptosis, and to determine the molecular signaling targets of t-Darrp.

7R01 CA114524 (Penson) 9/25/2009 - 7/31/2011
NCI Role: Co-investigator
Race, Comorbidity, Long-Term Prostate Cancer Outcomes

The major goal of this project is to explore the relationships among race, comorbidity, and logn-term prostate cancer outcomes.

5R01 CA106176 (El-Rifai) 4/1/2010 - 3/31/2011
NCI Role: Co-investigator
Molecular Pathobiology of Barrett's Tumorigenesis

The major goal of this project is to discover novel diagnostic and/or prognostic molecular markers for Barrett's carcinomas.

5R01 CA142565 (Yankeelov) 5/1/2010 - 4/30/2015
NCI Role: Co-investigator
PET-MRI for Assessing Treatment Response in Breast Cancer Clinical Trials

The major goal of this project is to provide the breast cancer community with practical data acquisition and analysis protocols that facilitate the translation of advanced imaging technologies into clinical practice.

5R01 DK087962 (Fowke) 7/1/2010 - 6/30/2014
NIDDK Role: Co-investigator
Biomarkers of Obesity, Prostate Tissue Inflammation, and BPH Progression

The major goal of this project is to investigate the molecular/cellular and clinical associations among obesity, prostate inflammation, and prostate hyperplasia.

1R01 CA143094 (Lynch) 7/1/2010 - 6/30/2015
NIH Role: Co-investigator
Host MMP-Mediated Regulation of the Vicious Cycle of Prostate to Bone Metastases

The major goal of this project is to investigate how individual matrix metalloproteinases (MMPs) expressed by the host facilitate the metastasis of prostate cancer to bone by regulating the bioactivity and bioavailability of various growth factors and cytokines.

5R21 AR062880 (Archer-Swygert) 4/20/2012 - 3/31/2014
NIAMS Role: Co-investigator
Cognitive-Behavioral Based Physical Therapy: Improving Surgical Spine Outcomes

The major goal of this project is to study the efficacy of a brief cognitive-behavioral based PT (CBPT) intervention in patients at-risk for poor outcomes following lumbar spine surgery for degenerative conditions.

1P20 DK097782 (Hayward) 9/29/2012 - 7/31/2014
NIDDK Role: Co-investigator
Obesity, Inflammation, and Resistance to BPH

This project aims to determine the role of obesity in the development of benign prostatic hyperplasia (BPH).

1R03 CA173812 (Barocas) 1/1/2013 - 12/31/2014
NCI Role: Co-investigator
Trends in Surveillance for Localized Prostate Cancer and Barriers to Its Use

The major goal of this project is to identify differences in the patient and disease characteristics among men with prostate cancer who chose surveillance from two eras (1990's and 2010's).

1R03 CA173807 (Barocas) 1/1/2013 - 12/31/2014
NCI Role: Co-investigator
The Quality of Care in Evaluating Patients Suspected of Having Bladder Cancer

This project aims to determine the current quality of evaluation of patients with hematuria, identify racial variation in the timely and complete evaluation of hematuria and determine the underlying reasons for such variation.

IRG 58-009-53 (Esbenshade) 1/1/2013 - 12/31/2013
ACS-IRG Role: Co-investigator
ALL-Active: A Family-Based Lifestyle Program for Pediatric Acute Leukemia Patients

The major goal of this project is to develop a feasible and acceptable family-based nutrition and exercise intervention for overweight or overweight at risk patients during the maintenance phase of the ALL therapy, which can be further tested for efficacy in a larger scale randomized clinical trial.

1R21 HL117676 (Bastarache) 4/1/2013 - 3/31/2015
NHLBI Role: Co-investigator
Free Hemoglobin Potentiates Pulmonary Vascular Dysfunction in Acute Lung Injury

The major goal of this project is to determine whether free hemoglobin is an important determinant of pulmonary vascular dysfunction in clinical ALI/ARDS.

5R21 HL112656 (Ware) 5/1/2013 - 4/30/2014
NHLBI Role: Co-investigator
Inflammatory and Epithelial Injury

The major goal of this project is to validate SP-D and IL-8 as predictors of clinical outcome in 888 patients enrolled in the NHLBI ARDS Network Fluid and Catheter Treatment Trial (FACTT).

VUMC 41268 / **CE-12-11-4667** (Penson) 9/1/2013 - 8/31/2016
PCORI Role: Co-investigator
Generating Critical Patient-Centered Information for Decision Making in Localized Prostate Cancer

The major goal of this project is to better align clinical decision-making with individual patient values and preferences and inform patient choice of healthcare providers based on the quality of care provided.

1R01 HS022640 (Penson) 9/30/2013 - 9/29/2018
AHRQ -CHOICE Role: Co-investigator
Comparative Effectiveness of Treatments for Localized Prostate Cancer

The major goals of this project are to compare the effectiveness and harms of contemporary surgery, radiation, and AS, to identify patient-level characteristics that influence the comparative effectiveness and harms of treatment, and to evaluate the association of quality of care with clinical and patient-reported outcomes.

Pilot Project (Ware) 10/1/2013 - 3/31/2015
NIH/VUMC Role: Co-investigator
VU Center for Molecular Toxicology Pilot Project

Funding awarded by the Vanderbilt University Center for Molecular Toxicology (NIEHS P30 ES000267).

5UM1 CA186689-02 (Berlin) 3/1/2014 - 2/28/2019
NCI Role: Co-investigator
ViKTriY Early Clinical Trials Consortium

The ultimate purpose of this project is to define better approaches for the development of novel anticancer agents that capitalize on the ability to characterize tumors molecularly and find appropriate biomarkers to select patients most likely to respond to specific agents.

5R01HL126176-02 (Ware) 12/1/2014 - 5/31/2021
NHLBI Role: Co-investigator
The GOLD Study: Goal of Open Lung Ventilation in Donors

The current supply of donor lungs is inadequate to meet the growing demand. Well-designed studies of scientifically compelling donor management strategies are urgently needed to improve the quality and availability of donor lungs. The proposed studies will test a new mechanical ventilator strategy to optimize donor lung function in order to increase utilization of donor lungs for transplantation.

1K23 NS091524-01 (Patel) 4/1/2015 - 3/31/2020
NINDS Role: Co-investigator
DASH (Decreasing Adrenergic or Sympathetic Hyperactivity) After TBI Study

The major goals of this project are to determine the effect of adrenergic blockade on short-term ICU outcome after severe TBI, to determine the effect of adrenergic blockade on long-term cognitive and functional outcomes, and to determine the effect of adrenergic blockade on autonomic endpoints after severe TBI.

W81XWH-15-1-0259 (Fowke) 9/1/2015 - 8/31/2017
DOD Role: Co-investigator
Magnesium Predicts High-Grade Prostate Cancer and a Poorer Prognosis among Black and White Men

The major goal of this project is to extend our prior epidemiologic analysis of Mg and PC in white men to evaluate the Mg-PC association among black men.

2K24HL103836-06 (Ware) 6/1/2016 - 3/31/2021
NHLBI Role: Co-investigator
Midcareer Investigator Award in Patient-Oriented Research in Acute Lung Injury

The overall goal of this application is to provide support for Dr. Ware to continue to build and expand her research and mentoring programs in patient-oriented research in acute respiratory distress syndrome, a common cause of acute lung failure. In addition to providing support for mentoring activities, this award will support new research in the causes of acute respiratory distress syndrome after lung transplantation, the most common cause of death in the acute period after lung transplantation.

5R21TR001723-02 (Aronoff) 9/1/2016 - 7/31/2018
NCATS Role: Co-investigator
Repurposing Misoprostol for Clostridium Difficile Colitis as Identified by pheWAS

The major goal of this project is to define the optimal dose and timing of administration of oral misoprostol in a mouse model of relapsing CDI and to determine the correlates of protectioni by misoprostol in a mouse model of relapsing CDI.

5R01CA207401-02 (Hull) 12/20/2016 - 11/30/2021
NCI Role: Co-investigator
Increasing HPV Vaccination in Community-Based Pediatric Practices

Our central goal is to identify the optimal approach to implementing an evidence-based intervention for the uptake and completion of HPV vaccine among adolescents receiving care in the community, guided by implementation science theory.

217-68001-26352 (Hull) 4/15/2017 - 4/14/2018
US Department of Agriculture Role: Co-investigator
Children Eating Well (CHEW) Smartphone Application for WIC families

2P30DK058404-16 (Peek) 8/1/2017 - 5/31/2022
NCI Role: Co-investigator
Molecular and Cellular Basis for Digestive Diseases

The overall goal of the GiSMC is to provide murine models of bariatric surgery using procedures designed to reflect those performed in humans, liver and small bowel transplantation, and unique customized surgical models adapted to the needs of VDDRC members.

1R01 HL135849-01 (Ware) 8/1/2017 - 4/30/2021
NHLBI Role: Co-investigator
Targeting Cell-Free Hemoglobin in Sepsis to Reduce Lung Microvascular permeability: Mechanistic and Translational Studies

Our primary goal is to translate these findings to new targeted therapies that will be tested in our novel human lung model as preparation for rapid translation to clinical trials in sepsis. In Aim 1, we will study the mechanism by which CFH increases microvascular permeability and acute lung injury through induction of mitochondrial oxidative injury and dysfunction in the isolated human lung, clinically relevant models of sepsis-induced ARDS and cultured pulmonary microvascular endothelial cells.

5R01HD090061-02 (Gaddy) 9/1/2017 - 5/31/2022
NIH/NICHD Role: Co-investigator
Determining the Contribution of Zinc Deficiency to Perinatal Group B Streptococcus Infections

This work will identify novel biomarkers for increased disease risk and cost-effective dietary or chemotherapeutic strategies that could improve pregnancy outcomes.

1R01CA225005-01 (Friedman) 7/1/2018 - 6/30/2023
NCI Role: Co-investigator
Research Into Visual Endpoints and RB Health Outcomes After Treatment

The RIVERBOAT Consortium: The overall goal of this effort is to organize the first and largest international multicenter, multi-racial and ethnic consortium of retinoblastoma (RB) survivors to study health outcomes and interrogate genotype-phenotype correlations of disease presentation.

VUMC71798 (Penson) 10/1/2018 - 9/30/2021
UCLA/PCORI Role: Co-investigator
Using PCORI Data to Drive Better Decisional Quality for Men with Localized Prostate Cancer

The purpose of this research is to further close the gap between evidence development and implementation of evidence into practice.

1R01CA230352-02 (Barocas) 4/1/2019 - 3/31/2024
NCI Role: Co-investigator
10-year Comparative Effectiveness and Harms of Treatments for Prostate Cancer

Our aim is to expand upon an established population-based cohort of approximately 3,000 men diagnosed with localized prostate cancer between 2011 and 2012, by collecting 10-year clinical and patient-reported information. This will enable comparisons of oncologic outcomes and quality of life outcomes among the treatment options, thereby providing information to power shared-decision making processes between patients and their providers. Specific Aims are: 1) Compare clinical outcomes in men undergoing contemporary radiation therapy, surgery and active surveillance for localized prostate cancer approximately 10 years after diagnosis; 2) Compare 10-year patient-reported outcomes among men undergoing contemporary radiation therapy, surgery and active surveillance for localized prostate cancer; and 3) Explore the extent to which patient characteristics modify comparative effectiveness and harms.

1R01CA240093-01 (Friedman) 8/1/2019 - 7/31/2024
NCI Role: Co-Investigator
Enhancing Cancer Care of Rural Dwellers Through Telehealth and Engagement (ENCORE)

The specific aims of this proposal are to: 1) evaluate the clinical effectiveness of a multi-level telehealth-based intervention for rural hospitals consisting of provider access to tumor board expertise that incorporates disease, patient, and molecular tumor characteristics, together with patient access to a supportive care intervention to improve cancer care delivery; and 2) identify the facilitators and barriers to future larger scale dissemination and implementation of the multi-level intervention, designed to enhance quality rural cancer care delivery.

1R01DK129624-01 (Reynolds) 7/1/2021 - 6/30/2026
NIDDK Role: Co-Investigator
Stress and Anxiety Effects on Overactive Bladder: A Controlled Study

The proposed, interdisciplinary research that includes experts in Urology, Psychology, and chronic pain research will contribute to the fundamental knowledge of how psychology relates to bladder sensitivity and to psychological burdens in people with overactive bladder and how this can be measured effectively. This will allow future studies in which interventions to improve bladder health and incontinence can be implemented and outcomes recorded, with the goal of improving bladder health.

1R21GM144915-01 (Bastarache) 12/1/2021 - 11/30/2025
NIGMS Role: Co-Investigator
The Sepsis ClinicAl Resource And Biorepository (SCARAB) Project

Here we propose to create a unique resource, the Sepsis ClinicAl Resource And Biorepository (SCARAB) registry comprising prospectively enrolled sepsis patients and critically ill control patients, their complete, de-identified medical records, automated phenotyping algorithms, and a complement of serial biological specimens to be used by the sepsis research community.

1R01HL158906-01 (Ware) 9/1/2021 - 8/31/2025
NHLBI Role: Co-Investigator
Haptoglobin 2 variant and endothelial glycocalyx shedding in sepsis-induced ARDS

Our primary goal is to translate these findings to new targeted therapies that will be tested in our novel isolated human lung model as preparation for rapid translation to targeted clinical trials in sepsis.

1UG3CA260318-01 (Friedman) 9/22/2021 - 8/31/2023
NCI Role: Co-Investigator
CAUSAL: Cohort to Augment the Understanding of Sarcoma Survivorship Across the Lifespan

Major Goals: Sarcomas represent a rare and highly heterogeneous subtype of tumors that may develop across the lifespan. In the United States (US), there are approximately 14,000 new cases annually, with approximately 65% survival. Aside from those included in pediatric cancer survivor cohort studies, there are no sarcoma survivor cohorts in which to systematically study recurrence, organ toxicity, function, quality of life, and survival as well as their predictors. We propose to address these critical gaps in knowledge by establishing a cohort of approximately 2100 sarcoma survivors through the Vanderbilt University Medical Center (VUMC) Sarcoma Treatment Center, which is amongst the largest sarcoma programs in the US, in existence since 1987. In this cohort, we will systematically collect repeated information on disease, treatment, response, relapse, treatment-related toxicity, sociodemographics, lifestyle, functional status, quality of life, physical health outcomes, and survival, together with biospecimens (tumor tissue and peripheral blood samples).

VUMC9441/2017-68001-26352 (Hull) 04/15/2017 - 04/30/2022
University of Kentucky/US Dept of Agriculture Role: Co-Investigator
Children Eating Well (CHEW) Smartphone Application for WIC Families

The objectives of this proposal are to: 1) Develop and maintain version 2.0 of the CHEW app in English and Spanish, and disseminate it to the WIC program to implement in WIC clinics across TN (Extension); 2) Conduct process, outcome, and economic evaluation of the CHEW app implementation in the TN WIC program (Research); and 3) Train high school, undergraduate, and graduate students and post-doctoral fellows in the use of technologies for childhood obesity prevention (Education).

1R01DK128293-01A1 (Reynolds) 9/24/2021 - 07/31/2025
NIDDK Role: Co-Investigator
Central Sensitization and Psychosocial Impacts on Overactive Bladder

Major Goals: The proposed, interdisciplinary research that includes experts in Urology, Psychology, and chronic pain research will contribute to the fundamental knowledge of how central sensitization relates to bladder sensitivity and to psychological burdens in people with overactive bladder and how this can be measured effectively.

VUMC87724 (Miller) 08/03/21 - 12/31/21
Mayo Clinic Arizona Role: Biostatistician
Prospective Randomized Double Blind Clinical Trial to Compare Holum Laser Lithotripsy With and Without Moses Laser Technology for the Ureteroscopic Treatment of Nephrolithiasis

Major Goals: The objectives of the EDGE Consortium is to (i) improve outcomes in patients suffering with kidney stone disease by conducting high quality translational research, (ii) to provide an infrastructure to facilitate such high quality research in collaboration with clinicians, scientists and researchers at Mayo Clinic Arizona and other member Sites.

1R01DK129202-01A1 (Hsi) 04/01/2022 - 03/31/2025
NIDDK Role: Co-Investigator
Randomized Trial of Empiric Versus Selective Preventative Strategies for Kidney Stone Disease

This study will evaluate comparative effectiveness of selective versus empiric intervention strategies on urinary risk profiles of kidney stone patients.

1U01HL163303 (Ware) 08/05/2022 - 07/31/2027
NHLBI Role: Co-Investigator
Peri-operative factors that drive cell-free hemoglobin-mediated primary graft dysfunction

Major Goals: We will establish a three-center study to determine how CFH causes PGD and how clinical management alters accumulation and oxidation of CFH, laying the groundwork for clinical trials targeting CFH to reduce risk of PGD.

1R01AI176521 (Goettel) 04/01/2023 - 03/31/2027
NIAID Role: Co-Investigator
Characterizing antibody responses to HIV-1 vaccination in next-generation immune humanized mice

Major Goals: We have developed a novel HIS mouse strain expressing human leukocyte antigens (HLA)-DQ and HLA-A in the absence of murine major histocompatibility complex (MHC) I/II (to ensure human T cell selection on a more appropriate molecules in the mouse thymus) in combination with human CSF1 knocked into the murine Csf1 locus. We will leverage this new translational HIS platform to: i) Determine the scope of the human adaptive immune response to infection with HIV-1 R5 virus, ii) Determine the neutralization ability of, define the Env epitopes targeted by, and delineate the sequence features for the human adaptive immune response to HIV-1 immunization, and iii) assess a novel vaccination strategy using optimized multivalent immunogens for broad neutralizing antibodies (bNAb) elicitation.

1R21DK133742 (Kavoussi) 04/01/2023 - 03/31/2025
NIDDK Role: Co-Investigator
A Navigational System for Endoscopic Kidney Stone Surgery

Major Goals: Our overall goal is to create a navigational system that makes stone localization and tracking within the renal collecting system easier and more accurate for the surgeon. Toward this goal, our specific objective in this proposal is to test the hypothesis that a navigational system during endoscopic stone surgery can improve stone free rates which would mitigate recurrent surgeries or complications from residual fragments.