

**BIOGRAPHICAL SKETCH**

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NAME: **Jeffrey D. Blume, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): **jblume99**

POSITION TITLE: **Professor of Data Science; Quantitative Foundation Associate Dean for Academic and Faculty Affairs in Data Science**

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
State University of New York at Buffalo	BS	05/94	Statistics
The Johns Hopkins University	PhD	08/99	Biostatistics

**A. Personal Statement**

I am Professor and Quantitative Foundation Associate Dean at the University of Virginia School of Data Science. I am a Biostatistician by training and I work on methods for prediction modeling, statistical inference, and clinical trials. My recent research has focused on prediction modeling (especially in the presence of missing data), high-dimensional model selection, post-selection inference, statistical inference in large-scale data (e.g., second-generation  $p$ -values, false discovery rates), mediation modeling and clinical trials (mostly diagnostic imaging trials). I am a leading expert in Likelihood methods for measuring statistical evidence and inventor of the second-generation  $p$ -value (**Blume et al., 2018, *PLOS One*** and **Blume et al., 2019, *The American Statistician***). I am co-PI of a NCI-funded R01 that examines racial disparities in lung cancer screening, a project that has received considerable attention and for which I, and my Co-PI Melinda Aldrich, were awarded the Vanderbilt's Chancellor's Award for Research on Equity, Diversity and Inclusion.

My collaborative experience is quite diverse, with collaborative work in diagnostic and cancer trials, radiology trials, biomedical research in nephrology and biochemistry, women's health, and fMRI studies. I previously served as Deputy Director of Biostatistics and Data Management Center for American College of Radiology Imaging Network (ACRIN), an NCI funded cooperative group that specializes in clinical trials evaluating new imaging technology. I have been the lead statistician in numerous large-scale multicenter trials, and I currently serve on several data safety monitoring boards. I have extensive experience in the design, conduct and analysis of clinical trials, and statistical methods for estimating and applying ROC curves.

My lab has graduated PhD students with diverse methodological contributions: Dr. Christina Saunders proposed a novel estimation framework for mediation models. This new framework provides an analytical solution for the variance of the mediation effect and allows for multiple mediators and predictors of interest (Saunders and **Blume**, 2017, *Biostatistics* and 2019, *Multivariate Behavioral Research*). Dr. Sarah Mercaldo showed how to optimize the prediction accuracy of prediction models in the presence of missing data (Mercaldo and **Blume**, 2018, *Biostatistics*). She also invented a 'bagged empirical null  $p$ -values' which has improved statistical properties in high dimensional settings (Mercaldo and **Blume**, under review arXiv:1707.05833). Dr. Derek Smith developed novel empirical Bayes and shrinkage estimators for use in Biomedical and public health research (Smith, Smith, Billings and **Blume**, 2017, *Diagnostic and Prognostic Research*). Dr. Yi Zou developed a variable selection algorithm based on second-generation  $p$ -values that is very accurate (Zuo, Stewart, **Blume** in *The American Statistician* 2022 and *F1000Research* 2022). Dr. Megan Murry has established the connection between equivalence tests and second-generation  $p$ -values, and she developed study planning tools for second-generation  $p$ -values (Murray and Blume 2021, *F1000Research*). I currently mentor 2 PhD students: Valerie Welty, a sixth-year PhD candidate working on false discovery rates and second-generation  $p$ -values and Gia Smith, a first-year PhD student in Data Science working on lung cancer screening models.

## B. Positions, Scientific Appointments, and Honors

### Positions and Scientific Appointments

2021-present	<b>Professor of Data Science</b> , University of Virginia School of Data Science
2021-present	<b>Quantitative Foundation Associate Dean for Academic and Faculty Affairs</b> , University of Virginia School of Data Science
2018 – 2021	<b>Director of Graduate Education</b> , Data Science Institute at Vanderbilt
2018 – 2021	<b>Vice-Chair for Education</b> , Department of Biostatistics
2012 – 2018	Member, NIH Study Section: <i>Biostatistical Methods and Research Design</i> (BMRD)
2012 – 2015	Faculty Senator, Vanderbilt University
2009 – 2014	Associate Editor, <i>Clinical Trials: Journal of the Society of Clinical Trials</i>
2009 – 2014	<b>Founding Director</b> , Biostatistics Collaboration Center, Department of Biostatistics, Vanderbilt University School of Medicine
2008 – present	<b>Director of Graduate Studies</b> , Department of Biostatistics, Vanderbilt University School of Medicine
2008 – present	<b>Associate Professor</b> , Department of Biostatistics, Vanderbilt University School of Medicine
2008	<b>Associate Professor</b> , Center for Statistical Sciences, Brown University
2007 – 2008	Member, Intuition Review Board, Brown University
2006 – 2016	Invited Faculty, Clinical Trials Methodology Workshop, Radiological Society of North America [January of each year, excluding 2010 & 2011]
2005 – 2012	Ad Hoc Reviewer, NIH Study Sections and Special Emphasis Panels (10 meetings)
2005 – 2008	<b>Deputy Director</b> , American College of Radiology Imaging Network Biostatistics and Data Management Center, Brown University
2005 – 2007	<b>Assistant Professor</b> , Obstetrics and Gynecology, Brown Univ. Medical School
2005 – 2008	<b>Assistant Professor</b> , Center for Statistical Sciences, Brown University
1999 – present	Member, American Statistical Association, International Biometric Society, Institute of Mathematical Statistics, and Society for Clinical Trials
1999 – 2005	<b>Assistant Professor (Research)</b> , Center for Statistical Sciences, Brown University
1996 – 1998	Teaching Associate, The Johns Hopkins School of Public Health
1995 – 1999	National Eye Institute Traineeship in Clinical Trials, Johns Hopkins School of Public Health
1993 – 1994	Biostatistics Intern, Genetics Institute, Inc., Cambridge, MA

### Honors

2020	Chancellor's Award for Research on Equity, Diversity and Inclusion, Vanderbilt University
2019	Spinoza Chair in Medicine, University of Amsterdam, The Netherlands.
2017, 2019	Golden Apple Award for Excellence in teaching, Vanderbilt University (graduate student body)
2015	Outstanding Faculty Mentor, Vanderbilt University (graduate student body)
2014	<i>Patrick G. Arbogast Award</i> for best collaborative publication, Vanderbilt University
2004	Award for Outstanding Contribution, American College of Radiology Imaging Network
2003	NIH loan repayment program recipient [via NCI, 2 awards]
1998	Travel Award, Finalist, Society for Clinical Trials Student Paper Competition, Atlanta GA
1998	Helen Abby Award for Excellence in Teaching, Department of Biostatistics, Johns Hopkins
1997	Advising, Mentoring, and Teaching Recognition Award, Johns Hopkins School Public Health

## C. Contributions to Science

### **Clinical Trials in Imaging and Diagnostic Medicine**

I have extensive experience in the development, operation, analysis, and methodological aspects of clinical trials. I served as Deputy Director of the Biostatistics and Data Management Center for ACRIN (now ACRIN-ECOG). ACRIN trials frequently re-shaped the standard of care for imaging procedures in Radiology and Oncology. The trials I led ranged in scope and design: a retrospective reader study of CT image segmentation software for measuring brain tumors volume, a medium sized cohort study of MRI imaging in women with stage III breast cancer, studies of multislice CT angiography of the brain and cervicocranial vessels, and studies of computer assisted diagnosis (CAD) algorithms for MRI in detecting breast cancer, a large-scale reader study of MRI Spectroscopy for localizing prostate cancer, and a large-scale prospective screening trial of whole breast ultrasound. I developed an approach for projecting sample sizes in diagnostic studies where the objective is to

estimate the area under the ROC curve. The approach is particularly useful because there is a minimum and maximum sample size that would ever be needed, regardless of the underlying assumptions.

1. **Blume JD**. "Bounding Sample Size Projections for the Area under a ROC Curve." *Journal of Statistical Planning and Inference*, 2009, 139(3), 711-721. PMID: PMC2631183
2. Weinreb JC, **Blume JD**, Coakley FV, Wheeler TM, Cormack JB, Sotito CK, Cho H, Kawashima A, Tempany-Afdhal C, Macura KJ, Rosen M, Gerst S, Kurhanewicz J. "Prostate cancer: sextant localization at MR imaging and MR spectroscopic imaging before prostatectomy--results of ACRIN prospective multi-institutional clinicopathologic study." *Radiology*, 2009 Apr;251(1):122-33. PMID: PMC2663583
3. Berg W, **Blume JD**, Cormack J, Mendelson E, Lehrer D, Bohm-Velez M, Pisano E, Jong R, Evans W, Morton M, Mahoney M, Hovanessian-Larsen L, Barr R, Marques H, Boparai K, and the ACRIN 6666 Investigators. "Combined Screening with Ultrasound and Mammography vs Mammography Alone in Women at Elevated Risk of Breast Cancer." *JAMA*, 2008 May 14; 299(18) 2151-2163. PMID: PMC2718688
4. Berg W, **Blume JD**, Adams A, Jong RA, Barr RG, Lehrer DE, Pisano ED, Evans WP, Mahoney M, Larsen LH, Gabrielli G, Mendelson EB. "Reasons Women at Elevated Risk of Breast Cancer Refuse Screening Breast MRI: ACRIN 6666." *JAMA*, 2010, January 254(1):79-87. PMID: PMC2811274. PMID: 20032143

### Lung Cancer Screening and Diagnosis

In close collaborations, I developed a prediction model for risk of lung cancer in patients being considered for surgical resection, showed that the utility of PET imaging for the diagnosis of lung nodules varies widely across the country and depends critically on geography, examined racial disparities in lung cancer survival, and proposed revised eligibility guidelines for lung cancer screening for African Americans.

1. Deppen SA, **Blume JD**, Aldrich MC, Fletcher SA, Massion PP, Walker RC, Chen HC, Speroff T, Necessary CA, Lambright ES, Nesbit, JC, Putnam JB, Grogan EL. "Predicting Lung Cancer Prior to Surgical Resection in Patients with Lung Nodules." *J Thorac Oncol.*, 2014, Aug. PMID: 25170644 PMID: PMC4272613
2. Deppen SA, **Blume JD**, Kensinger CD, Morgan AM, Aldrich MC, Massion PP, Walker RC, McPheeters ML, Putnam JB Jr, Grogan EL. "Accuracy of FDG-PET to diagnose lung cancer in areas with infectious lung disease: a meta-analysis." *JAMA*, 2014, 312(12):1227-36. PMID: 25247519 PMID: PMC4315183
3. Jones CG, Mercaldo S, **Blume JD**, Wenzlaff AS, Schwartz AG, Chen H, Deppen S., Bush WS, Crawford, DC, Chanock SJ, Blot WJ, Grogan EL, Aldrich MC. Racial disparities in lung cancer survival: The contribution of stage, treatment, and ancestry. *Journal of Thoracic Oncology*, Jun 2018; s1566-0864(18)30682-8. PMID: PMC6153049
4. Aldrich MC, Mercaldo SF, Sandler KL, Blot WJ, Grogan EL, **Blume JD**. Evaluation of USPSTF Lung Cancer Screening Guidelines Among African American Adult Smokers. *JAMA Oncol.*, June 27, 2019. doi:10.1001/jamaoncol.2019.1402 PMID: 31246249 PMID: PMC6604090

### Likelihood Methods for Measuring Statistical Evidence

I have published a number of works that have advanced the field of evidential likelihood methods considerably. I have carefully explained the philosophical framework unique evidential quantities (the measure of the strength of evidence, the error rate, and the false discovery rate) and its impact on multiple testing and repeated examination of accumulating data. This framework explains why likelihood methods handle multiple testing so naturally while maintaining control of the probabilities of observing misleading and weak evidence. I have also published on (1) discrete-time corrected Brownian motion approximations for the probability of generating misleading evidence in study designs that continually re-examine accumulating; (2) robust likelihoods for generalized linear models that incorporate clustered data; (3) a framework for measuring evidence of cost-effectiveness; (4) a model selection strategy that minimizes the probability of observing misleading evidence in regression models with correlation predictors; (5) a comprehensive tutorial on Likelihood methods that continues to receive significant attention; (6) a framework for assessing evidence of non-inferiority in Clinical Trials; and (7) an applications of Likelihood methods in fMRI imaging studies where massive multiple testing problems exist. I have been invited to present over 30 seminars and short courses on Likelihood methods at universities, national meetings, the National Institutes of Health, the Food and Drug Administration (CDER and CDRH), pharmaceutical and biotechnology companies, and contract research organizations.

1. **Blume JD**. Likelihood and its evidential framework. In: Dov M. Gabbay and John Woods, editors, *Handbook of The Philosophy of Science: Philosophy of Statistics*. San Diego: North Holland, 2011, pp. 493-511.
2. **Blume JD**, Su L, Acosta L, McGarvey S. "Statistical Evidence for GLM parameters: A Robust Likelihood Approach". *Statistics in Medicine*, 2007, July; 26(15): 2919-36. PMID: 17211856
3. Wang SJ and **Blume JD**. "An evidential approach to non-inferiority clinical trials." *Journal of Pharmaceutical Statistics*, 2011, September 10(5): 440-447. PMID: 21928286
4. **Blume JD**. "How to choose a working model for measuring statistical evidence about a regression parameter". *International Statistical Review*, 2005; 73(2): 351-363.

### Women's Health

I have collaborated on a variety of topics in women's health: clinical predictors of endometritis; clinical predictors of bacterial vaginosis; association between maternal age and postneonatal death; computer intervention to increase contraceptive use; techniques for the evaluation of cervical dysplasia sampling; predicting pregnancy viability; added value of Urodynamic evaluations for female urinary incontinence; and systematic reviews of treatments for overactive bladder.

1. Plante B, Phipps M, **Blume JD**, Lambert-Messerlian G, Shackelton R, Canick J. A multiple marker model to predict pregnancy viability when progesterone is indeterminate. *The Journal of Reproductive Medicine*, 2008; 43(4): 243-9. PMID:18472646
2. Phipps MG, **Blume JD**, and DeMonner, SM. Young maternal age associated with increased risk of postneonatal death. *Obstet Gynecol.*, 2002; 100(3): 481-6. PMID:12220767
3. Hartmann KE, McPheeters ML, Biller DH, Ward RM, McKoy JN, Jerome RN, Micucci SR, Meints L, Fisher JA, Scott T, Slaughter JC, **Blume JD**. "Treatment of Overactive Bladder in Women." *Evidence Report/Technology Assessment No. 187*. AHRQ Publication No. 09-E017; Rockville, MD: Agency for Healthcare Research and Quality, August 2009 (187);1-120. PMID: 19947666 PMCID: PMC4781496
4. Reynolds WS, McPheeters M, **Blume J**, Surawicz T, Worley K, Wang L, Hartmann K. "Comparative Effectiveness of Anticholinergic Therapy for Overactive Bladder in Women: A Systematic Review and Meta-analysis." *Obstet Gynecol.*, 2015 Jun;125(6):1423-32. PMID: 26000514.

### Development of a new graduate programs in Biostatistics and Data Science

In 2011, I established a graduate program in Biostatistics at Vanderbilt University. The program is unique in integrating a curriculum that is nondenominational with respect to the foundations of statistical inference, modern in its emphasis on computing and teaching of statistical principles, progressive with regression modeling strategies, and aggressive in involving students in biomedical research and improving communication skills. I was the co-director of Vanderbilt's Big Biomedical Data Science (BIDS) Training Program, which prepares future leaders of the biomedical community through training in predictive analytics, computing infrastructure, software tool development, and big data analytics. In 2018, I established the MS program in Data Science at Vanderbilt University with a progressive curriculum. I am overseeing the development and execution of the PhD, MS, and Undergraduate programs in Data Science at the University of Virginia.

1. **Blume JD** "Likelihood Methods for Measuring Statistical Evidence." *Statistics in Medicine*, 2002 Sept; 21(17): 2563-2599. PMID: 12205699
2. **Blume JD** and Peipert JF. "What your statistician never told you about P-values." *Journal of the American Association of Gynecologic Laparoscopists*, 2003; 10(4), 439-444. PMID: 14738627
3. **Blume JD** and Royall RM. "Illustrating the law of large numbers (and confidence intervals)." *The American Statistician* 2003; 57(1): 51-57. Doi: 10.1198/0003130031081
4. **Blume JD** and Peipert JF. "Randomization in controlled clinical trials: Why the flip of a coin is so important!" *Journal of the American Association of Gynecologic Laparoscopists*, 2004; 11(3): 320-325. PMID: 15559341

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