Personal Statement- Brandon Keith, MA

Research administration has been my passion for more than 20 years. Throughout my career, I have had the opportunity to serve in research administration and leadership roles across academic medicine, oncology and ophthalmology research, and clinical trials. My experience has included regulatory affairs, research compliance, clinical trial operations, and research program management, working collaboratively with faculty investigators, sponsors, academic institutional review boards, and multidisciplinary academic research teams. These experiences have reinforced my belief that effective research administration is essential to advancing scientific discovery and improving patient care.

I currently serve as Director of Clinical Research for the University of Colorado Department of Ophthalmology, where I am leading initiatives to strengthen research infrastructure, standardize operational processes, expand clinical trial opportunities, improve study activation timelines, and support investigator engagement. I enjoy building systems that allow faculty investigators and academic research teams to succeed while ensuring that research is conducted with integrity, accountability, and efficiency.

I believe NCURA plays a vital role in supporting research administrators through education, professional development, collaboration, and advocacy. As our profession continues to evolve, NCURA provides the resources and community needed to navigate new challenges while promoting excellence across the research enterprise. I have benefited greatly from learning alongside experienced colleagues, and I believe one of our greatest strengths as a profession is our willingness to share knowledge and support one another.

If elected as Member at Large, I would bring a collaborative, practical, and service-oriented perspective. I hope to contribute by promoting best practices, encouraging professional development, supporting research administrators at every stage of their careers, and ensuring that the perspectives of clinical research administrators are represented within NCURA. I am committed to fostering collaboration across institutions and helping strengthen the profession that has given me such a rewarding career.

It would be an honor to serve the NCURA membership and contribute to the organization's mission of advancing research administration through leadership, education, collaboration, and service.

Respectfully,

Brandon Keith, MA

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Summary

Highly motivated professional with over 20 years' experience in research administration, management, and compliance; Strong background in regulatory administration of oncology and ophthalmology clinical trials, including program development, study oversight, screening of research subjects, informed consent processes and subject enrollment, monitoring visits, contract and budgets, IRB processes, EMR systems, FDA/NCI/ICH/GCP regulations, team leading and training.

Education

Graduate Certificate, Public Health
University of South Florida, Tampa, FL

Master of Arts, American Studies/Political Science
University of South Florida, Tampa, FL

Bachelor of Arts, Political Science *(Cum Laude)*
University of South Florida, St. Petersburg, FL

Professional Experience

March 2026- Present
Clinical Research Program Director, University of Colorado-Anschutz, Dept of Ophthalmology, Denver, Colorado

- Provide strategic leadership and operational management for the Department of Ophthalmology clinical trials program, directing program planning and growth.
- Oversee the full lifecycle of ophthalmology clinical studies, including feasibility, start-up, patient recruitment, study execution, and close-out.
- Lead and mentor clinical research coordinators and regulatory staff, promoting high-quality study conduct, professional development, and adherence to SOPs and quality standards.
- Ensure regulatory and institutional compliance, maintaining adherence to FDA regulations, ICH-GCP guidelines, and IRB requirements while coordinating with research and regulatory offices at the University of Colorado Anschutz Medical Campus.
- Manage program partnerships and financial operations, including sponsor and CRO relationships, clinical trial budgets and contracts, and identification of new research opportunities to expand the department's clinical trials portfolio.

April 2025-March 2026
Director of Industry Operations, Western States Cancer Research, Denver, Colorado

- Led operational strategy and execution for oncology clinical trials across multiple consortium sites, overseeing study feasibility, site selection, timelines, deliverables, and risk mitigation to ensure alignment with regulatory and organizational goals.
- Directed cross-functional clinical research teams and program staff, including clinical research coordinators, while coordinating clinical operations, regulatory, data management, and research finance functions.
- Managed sponsor and stakeholder engagement, including negotiating study budgets and contracts and maintaining strong relationships with WSCR-NCORP leadership, investigators, and external partners to support successful research outcomes.

2017-October 2024

Senior Regulatory Compliance Officer, Rocky Mountain Cancer Centers, Denver, Colorado

- Oversaw regulatory lifecycle management for ~100 Phase I–IV oncology clinical trials, including site initiation, ongoing regulatory maintenance, and study closure across US Oncology Network and CRO-sponsored studies while ensuring compliance with ICH/GCP, FDA, and OHRP regulations.
- Managed IRB and FDA regulatory activities and study documentation, including preparation of essential regulatory documents, submission of INDs, development of quality improvement processes, and readiness for internal, sponsor, and FDA audits.
- Led operational coordination and staff development, onboarding and training research personnel, facilitating regulatory oversight meetings, implementing an electronic regulatory documentation system, and serving as team lead during a corporate merger with Sarah Cannon Research Institute.

2015- 2017

Research Coordinator/Regulatory Administrator-II, Colorado Cancer Research Program (NCI-NCORP Site), Denver, Colorado

- Managed regulatory oversight for ~70 oncology clinical trials across 19 consortium sites in Colorado and Wyoming, preparing and submitting IRB applications, amendments, continuing reviews, and safety reports to multiple IRBs including local IRBs and the NCI CIRB while ensuring compliance with ICH/GCP standards.
- Supported clinical trial operations from study start-up through close-out, including NCI and industry trial initiation, development of essential regulatory documents, EDC data entry, study visits, subject consenting, and coordination with investigators, coordinators, and research finance teams. Also, scheduled and completed patient study visits, data entry, sponsor communication and participation in feasibility reviews.
- Facilitated research communication, training, and compliance monitoring, onboarding new staff with Human Subjects Protection training, disseminating safety updates and protocol changes to investigators, maintaining investigator credentialing and regulatory training, and supporting sponsor monitoring visits and audits.

2011-2015

Research Compliance Administrator, Institutional Review Board, Division of Research Integrity and Compliance, University of South Florida, Tampa, Florida

- Served as IRB Compliance Officer for the University of South Florida system, overseeing regulatory review of biomedical, social-behavioral, and oncology clinical research conducted across affiliated institutions including Moffitt Cancer Center, VA hospitals, and regional health systems.
- Conducted regulatory pre-review and oversight of IRB submissions, including initial and continuing reviews, amendments, and safety reporting, ensuring compliance with HRPP policies, FDA/OHRP regulations, HIPAA, VA policies, and ICH/GCP standards.
- Supported IRB operations and researcher engagement, facilitating board meetings, documenting determinations, assisting investigators with protocol and consent development, conducting outreach to students and researchers, and supporting AAHRPP accreditation and FDA audit readiness
- Certified Institutional Review Board Professional (CIP #2142625, *expired*)

2002- 2011

Research Laboratory Supervisor, Department of Comparative Medicine, University of South Florida, St. Petersburg, Florida

- Oversaw operations of a university animal research laboratory, ensuring compliance with study protocols and federal regulations (FDA, GCP, USDA, OLAW, and IACUC) while collaborating with researchers, veterinarians, and regulatory staff to maintain a high-quality research program.
- Supervised and trained up to 15 research technicians, managing scheduling, performance evaluations, protocol compliance, and staff development while training new personnel on animal research regulations and procedures.
- Supported research infrastructure and compliance activities, including assisting students with protocol development, managing controlled substance records and equipment calibration, developing animal enrichment programs with veterinary staff, and maintaining certification as a Lab Animal Technician (LAT) through the American Association for Laboratory Animal Science (AALAS).

Additional Information:

-Knowledge and understanding of federal research regulations including FDA, OHRP, HHS, and VA guidelines, as well as pharmaceutical industry policies and procedures, general research methods, records management, team building and excellent communication skills
-Certified: Good Clinical Practice, Hazmat/ IATA/CITI; National Cancer Institute Human Subjects Protection
-Member-National Council of University Research Administrators (NCURA), May 2026
-Member- Association for Research in Vision and Ophthalmology (ARVO), March 2026
-Attended- National Conference for Association for Research in Vision and Ophthalmology, March 2026, Denver, CO
-Presenter: "Ethical Considerations of Past and Present: Institutional Review Boards" July 8, 2026, Denver, Colorado
-Presenter: "Data Review and Regulatory: Different Sides of the Same Coin" February 27, 2024, Denver, Colorado
-Presenter: "Ethical Considerations of Past and Present: Institutional Review Boards" May 19, 2022, Denver, Colorado
-Completed "Empathy for Customer Service Professionals" training, August 8, 2022
-Presenter: "GCP Guidelines in Clinical Trials" June 30, 2022, Denver, Colorado
-Experience working in non-profit, hospital, private and university research environments
-Attended "Diffuse Large B-Cell Lymphoma and iNHL Disease" lecture with Dave Maryanski, Oct 5, 2017, Denver, CO
-Attended "Head and Neck Cancer: The Scope of Contemporary Cancer Care" lecture with Dr. Andrew Nemechek November 15, 2016, Denver, Colorado
-Attended OHRP Conference "Partners in Research: How Institutions, IRBs, and Researchers Can Collaborate More Effectively. March 15, 2013, Orlando, Florida
-Attended OHRP Quality Assessment (QA) Workshop, February 19, 2014. St. Petersburg, Florida
-Proficient in Microsoft Office programs such as Word, Excel, PowerPoint, Teams, Publisher, Outlook and Publisher
-Proficient with EDC systems such as Medidata RAVE, Inform, Bioclinica and the iKnowMed EMR system
-Proficient in the use of electronic IRB systems (eIRB) and electronic systems (CTMS, GEMS, InfoED, CTSU, CREDIT, etc)
-USF Graduate Certificate in College Teaching, 2011
-Florida Association for Laboratory Animal Science Technician of the Year, 2010
-Attended the Florida Association for Laboratory Science Conference, August 7, 2010, Tampa, Florida
-Attended Jackson Labs Management Training, November 8-11, 2010, Jupiter, Florida
-Certified: American Association for Laboratory Animal Science, Laboratory Animal Technician
-Moderator: Southeast Regional Ethics Bowl, St. Petersburg College, St. Petersburg, FL. 2012, 2013, 2014
-Member-Pi Sigma Alpha Political Science Honor Society (2002-2004)
-Member- USF College of Arts and Sciences Honors Society (2002-2004)
-Staff Writer -*The Crow's Nest* University of South Florida campus newspaper (2002-2004)
-Prior work experience as a retail customer service manager (SteinMart Dept Store, St Petersburg, FL 1999-2002)