

## **KRISTIN HAMERNIK WEST**

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### **PROFESSIONAL SUMMARY**

I provide regulatory analysis and advice to academic research universities on federal regulations governing the conduct and funding of various types of research, including research involving animal or human subjects. I have extensive subject matter expertise in laws and regulations applicable to the academic research enterprises (e.g., Common Rule, Animal Welfare Act, export control regulations, conflict of interest regulations, lab safety regulations, research security regulations), as well as laws that more generally impact institutes of higher education (e.g., Title IX, FERPA, HIPAA, Clery Act). I am skilled in establishing and administering working groups of administrators and faculty members to develop policies and processes, as well as in drafting analysis documents and reports. I have expertise in providing counsel on the handling of audits and investigations by government regulators, as well as claims brought forward in litigation. I am also skilled in drafting legal documents common to all business enterprises (e.g., contracts, real estate transaction documents, corporate policies).

### **EMPLOYMENT HISTORY**

#### **Council on Governmental Relations (COGR), Washington, D.C. 2005**

March 12, 2020 to present: **Director, Research Ethics & Compliance**

#### **Duties:**

Analyze federal legislation concerning basic, animal and human subjects research and research administration.

Communicate analysis and advice to COGR member institutions through publications, webinars, and membership meetings.

Communicate the viewpoints and concerns of member institutions to federal regulatory agencies and foster the relationship between research institutions and research funding agencies.

#### **Emory University, Atlanta, GA 30322**

July 2015 to March 6, 2020: **Chief Compliance Officer**

August 2002 – July 2015: **Associate Vice President & Director of Research Compliance**

February 1999 - August 2002: **Senior Associate General Counsel**. (Note: I continued to hold this position/title while also serving as Associate Vice President and Director of Research Compliance, with dual reporting lines to the Vice President for Research Administration and the Senior Vice President and General Counsel.)

March 1989 - February 1999: **Associate General Counsel**

#### **Compliance Office Duties**

- Provide oversight of all university compliance activities and coordinate with operational units in designing and implementing strategies to ensure compliance with laws impacting the university's administrative, educational and research functions.
- Report directly to the Emory University Board of Trustees and Emory University's three Executive Vice Presidents.

- Review and interpret applicable laws and regulations for university operational units and assist units in developing policies, processes and tools necessary to ensure compliance therewith. Laws, regulations and policies on which I regularly provide advice, include, among others: Common Rule, FDA regulations, export control regulations (EAR, OFAC), Animal Welfare Act, biosafety and radiation safety laws/regulations, occupational health and safety regulations, DEA regulations, Title IX, Clery Act, privacy regulations including HIPAA, FERPA, and GDPR, and anti-discrimination and accessibility regulations (e.g., Title IX, Americans with Disabilities Act).
- Develop and utilize risk assessment tools and participate in the university-wide enterprise risk assessment and management process, using results to develop an annual compliance plan.
- Represent the university in interactions with government regulatory and funding agencies (e.g., NIH, HRSA, FDA, USDA, OCR), including negotiation/settlement of disputed findings.
- Provide legal and compliance advice to regulatory committees including Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Institutional Biosafety Committee.
- Establish and lead committees composed of faculty members and university administrators to develop recommendations, policies and processes on a variety of compliance issues (e.g., committee to improve university policy administration, committee to evaluate university's structure for ensuring compliance with export control regulations, committee to evaluate and improve policies on research integrity).
- Lead top-level compliance liaison committees composed of representatives from faculty and administrative/operational units to ensure solid lines of communication regarding compliance responsibilities and initiatives and to secure input for annual compliance plan and related auditing and monitoring goals.
- Conduct investigations in response to internal and external complaints, including investigation of whistleblower reports received via university-wide hotline for reporting non-compliance and fraud.
- Develop and implement compliance review and audit strategies to identify compliance areas requiring improvement and to measure success of compliance initiatives.
- Conduct for-cause and not-for-cause audits and develop corrective and preventative action plans to address identified deficiencies.
- Develop and conduct proactive educational and training programs regarding regulatory responsibilities and associated university policies.
- Serve as University Privacy Officer and Research Integrity Officer.
- Manage a staff of eight individuals, including four attorneys and four compliance specialists.
- Project Examples: Conduct of university-wide risk assessment project to measure compliance with NIH Grants Policy Statement, assess noted gaps and assist units in developing appropriate corrective action; conduct of investigations in response to NIH inquiries regarding potential foreign influence on research; led information privacy compliance project, including development/drafting of HIPAA and FERPA policies, forms, and training programs; establishment of university working group to analyze current export control administrative structure and processes and development of options for improvement; development of policies, forms, training materials and educational outreach program to instruct labs on the requirements for the use of controlled substances in research; review of current conflict of interest and conflict of commitment policies and associated training and disclosure mechanisms for employees; and development of a new process for the development, vetting and adoption of enterprise-wide policies.

**Office of General Counsel Duties:**

- Provided legal advice and recommendations to Emory University's president, vice presidents, deans and directors from all schools, divisions and departments with regard to the structure of various business and financial transactions; compliance review of transactions; and preparation of appropriate legal documentation for transactions.

- Negotiated, drafted and reviewed complex contracts, including agreements for multifaceted real estate transactions; agreements for the procurement and provision of goods and services; financing agreements; construction and architectural agreements; and documents related to tax exempt bond financing.
- Managed litigation including pre-trial investigation, witness preparation, coordination of discovery, selection and oversight of outside counsel, and conduct of settlement negotiations in multiple types of legal matters, including real estate, construction and zoning litigation; negligence claims; and bankruptcy and collection litigation.
- Oversight of legal issues concerning regulatory compliance and investigation of employee and governmental agency concerns.
- Development and drafting of university policies and procedures.
- Sample Matters: Provided legal advice and drafted documentation for development and construction of a new hospital complex in downtown Atlanta, which included a land swap with the U.S. government and associated city zoning issues; developed forms and processes for Student Loan Office to ensure compliance with federal financial aid requirements; drafted master procurement and independent contractor contract forms for use across campus; represented university in negotiations with state regulators concerning clean up of hazardous waste site; and managed claims and regulatory investigations stemming from accidental death of research employee, including development of communications and media strategy.

**July 1986 to February 1989: Federal Prosecutor, U.S. Department of Justice, Antitrust Division, Richard Russell Bldg., 75 Spring St., S.W., Atlanta, GA.**

**Duties:**

- Conducted investigations into and prosecuted violations of federal antitrust laws.
- Prepared pleadings, motions, legal memoranda, subpoenas, briefs and other legal documents and correspondence.
- Conducted grand jury sessions and trials.
- Selected as trial attorney through the U.S. Department of Justice Honors Program; received Outstanding Performance Rating in July 1988.

**LICENSES AND CERTIFICATIONS**

**Bar Admission:** Georgia

**Certified in Healthcare Research Compliance (CHCRC),** Health Care Compliance Association.

**EDUCATION**

**M.S. Pharmaceutical Outcomes & Policy; Drug Regulatory Affairs:** University of Florida, College of Pharmacy, Gainesville, Florida.

**J.D., Magna Cum Laude:** Mercer University Law School, Macon, Georgia.

**Honors:** Full Academic Scholarship; Member and Editor, Mercer Law Review; West Publishing's Hornbook Award; *Corpus Juris Secundum* Award; Lawyers Co-Operative Publishing's American Jurisprudence Awards in Property, Contracts, Domestic Relations, Constitutional Law, Torts and Remedies.

**B.A. in History, Summa Cum Laude:** University of Maryland at College Park.

**Honors:** Member of Phi Beta Kappa academic honor society.

**PROFESSIONAL ACTIVITIES AND SPEAKING ENGAGEMENTS**

**Adjunct Faculty, Loyola University Chicago School of Law: 2016 - Present.** Instructor for Advanced FDA Law in the LLM and MJ Online Programs in Health Law with a Concentration in Compliance.

**Health Care Compliance Association (HCCA) Research Compliance Academy Faculty 2008 -- Present.** Member of Health Care Research Compliance Certification Exam subcommittee.

Member of Association of Research Integrity Officers (ARIO) 2019 Annual Conference Planning Subcommittee and host for 2019 ARIO Annual Conference.

Member of the Editorial Board of the *Georgia Bar Journal*. 2002-2009.

**Publications:** *Research Compliance Professional's Handbook*, 3d Ed., *The Regulation of Research Using Animals*, HCCA, 2018; contributor to COGR's *Confidentiality Issues Related to Responding to Allegations of Research Misconduct*, August 2019.

**Invited Presentations 2005 – Present:** Numerous invited presentations, including presentations for the American Health Lawyers Association (AHLA), National Association of College and University Attorneys, National Council of University Research Administrators, American College of Laboratory Animal Medicine, Public Responsibility in Medicine and Research (PRIM&R), and the Health Care Compliance Association. Presentation titles available upon request.

**REFERENCES:**

Available upon request.