Health Sciences Law Group LLC

Julie Rusczek

Attorney

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My experience within the health care and life sciences industries positions me as a reliable go-to for the legal support and guidance needed by institutions, medical device and pharmaceutical companies, and other organizations in their pursuit of developing innovative new products and treatments. As a biology major in college with a life-long interest in science, I find that practicing law in the health care and life sciences space allows me to follow my passions on a daily basis.

My practice focuses on research compliance issues involving protection of human subjects under FDA and HHS regulations, research policy development and review, research agreement drafting and negotiation, and compliance with privacy laws and transparency reporting requirements.

My work touches the greater health care community as well, as I provide health systems, hospitals and long-term care providers with the legal guidance needed to address day-to-day health law issues, including informed consent, patient confidentiality, fraud and abuse, and medical staff matters.

I regularly speak at national conferences focusing on research issues, including PRIM&R's Advancing Ethical Research Conference and MAGI's Clinical Research Conference. I also co-author a chapter covering fraud and abuse in clinical research in Bloomberg BNA's treatise entitled *Health Law Fraud and Abuse: Practical Perspectives*.

Outside of the office, I enjoy hiking, camping, baking, and spending time with my husband and young son and daughter. My family frequently visits the coast of Maine and spends as much time on and near the water as possible, beachcombing, kayaking, sailing, and fishing. You'll often find *The New Yorker* or a Nathaniel Philbrick book on my nightstand and Celtic music playing in the family minivan (when the kids allow a departure from KidzBop and the *Frozen* soundtrack).

My experience includes:

- Assisting a health system to standardize system-wide approaches to negotiating clinical trial agreements and related documents such as confidentiality agreements, independent investigator agreements, and informed consent forms.
- Working with a disease-specific organization expand its registry study to international sites in several countries, including collaborating with foreign counsel in developing template agreements and informed consent forms and coordinating with CRO staff in negotiating with sites.
- Updating policies and procedures for a human subjects protection program in preparation for its reaccreditation by AAHRPP.
- Reviewing a hospital's medical staff bylaws, rules and regulations, and policies to help ensure compliance with state and federal regulations, accreditation standards, and best practices.
- Working with research sites to prepare for an FDA inspection of clinical trial documents and responding to FDA findings.

Bar Admissions

State Bar of Wisconsin

State Bar of Connecticut

U.S. District Court, Eastern District of Wisconsin

Education

University of Michigan Law School, J.D. *magna cum laude*, Order of the Coif

Williams College, B.A. *cum laude*