Katherine Leibowitz

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biography

For nearly 30 years, clients have relied on Katherine for her sharp, practical advice in life sciences and technology, with a particular focus on clinical trials and technology commercialization.

Katherine began her legal career at Hogan Lovells, a top global law firm, in Northern Virginia during the Dot Com boom, quickly establishing herself as the "go-to" lawyer for Internet, website, and e-commerce contracts. Notably, she was the first lawyer in the office to have desktop Internet access (after submitting a paper request). Website development and hosting, SaaS, clickwrap agreements, data rights, cybersecurity, privacy policies, and other emerging issues were new to both law and business, and Katherine guided clients through these complexities, helping transition brick-and-mortar businesses into the online world. She also worked with e-commerce startups and assisted with venture capital investments in emerging tech companies.

Her move to the Philadelphia office opened new doors in life sciences and medical technology. Katherine expanded her knowledge to include FDA regulations, HIPAA, human subject protection, fraud and abuse, reimbursement, financial disclosure, international data protection, and litigation risk management. She mastered and often led the development of clinical trial-related contracts, providing counsel throughout the clinical trial operations process. As the lead transactional attorney for numerous medical device multi-center studies, Katherine worked closely with clinical operations teams, general counsel, and C-suite executives. Her deep experience with device, drug, biologics and HCT/P studies distinguishes her in the clinical trials space.

In 2013, Katherine and her husband, Steve, founded their firm to make life sciences and technology contracting more accessible to small and mid-sized companies and

institutions. As a seasoned regulatory and technology transactional lawyer, Katherine offers a comprehensive range of services, from customized contract templates to complex negotiations and high-level legal counsel. Her unique blend of life sciences regulatory acumen, Dot Com know-how (now expanding into the "Wild West" of AI), and start-up experience positions her well to support sponsors of drug, device, and biologic trials, manufacturers, digital health companies, technology vendors, CROs, research institutions, and both established and emerging companies.

Katherine is passionate about helping her clients save lives and improve patient health. She is committed to empowering stakeholders across life sciences organizations, driving meaningful progress within the industry.

education

J.D., University of Pennsylvania Law School

B.A. in Philosophy, cum laude, Princeton University

memberships

Board of Directors, The Gateway School

American Bar Association

Philadelphia Bar Association Health Law Committee

Women Owned Law

bar admissions

Pennsylvania

presentations

"Negotiating Clinical Trial Agreements: Balancing the Interests of Sponsors and Healthcare Providers." Co-Speaker. Strafford CLE. November 19, 2024.

"Stump the Experts: Contracting and CTA Language." Co-Speaker. MAGI@home

Clinical Research Conference. October 25, 2024.

"Clinical Trial Agreements 103." Speaker. MAGI@home Clinical Research Conference. October 24, 2024.

"Indemnification: Who, What, and WHY it Matters." Co-Speaker. MAGI 2024 Clinical Research Conference. April 15, 2024.

"Indemnification: Basic." Co-Speaker. MAGI@home Clinical Research Conference. October 17, 2023.

"Managing Risk by Contract – Sponsor Perspectives on Clinical Trial Agreements." Speaker. CITI Program. October 5, 2023.

"Dissecting a Clinical Trial Agreements, Parts 1 and 2." Co-Speaker. MAGI Clinical Research Conference-2023 East.
May 21, 2023.

"Negotiating Clinical Trial Agreements: Balancing the Interests of Sponsors and Healthcare Providers." Co-Speaker. Strafford CLE.
April 26, 2023, and encore presentation July 11, 2023.

"Cyberliability and Finding the Balance on Data Security Practices." Co-Speaker and Chair. MAGI Clinical Research Hybrid Conference.
May 3, 2022.

"Unanticipated Problems & Adverse Events." Session Chair. MAGI Clinical Research Hybrid Conference.
May 2, 2022.

"Cybersecurity in CTAs and Vendor Agreements: Proactive Management vs. Cleaning Up the Mess."
Speaker. SCOPE Summit for Clinical Ops Executives.
February 9, 2022.

"Clinical Trials in a Post-COVID World: Three Legal Perspectives."
Co-Speaker. Philadelphia Bar Association Health Law Committee.
October 6, 2021.

"Cyberliability and Finding the Balance on Data Security Practices."
Session Leader and Panelist. MAGI Clinical Research vConference 2021.

May 5, 2021.

"Risky Business: A CTA Case Study Involving Subject Injury & Indemnification."
Session Chair. MAGI Clinical Research vConference 2021.
May 3, 2021.

"Dissecting a Clinical Trial Agreement."
Panelist. National Conference of University Research Administrators (NCURA)
Financial Research Administration (FRA) Conference.
March 16, 2021.

"Into the Abyss: Subject Injury and Indemnification."
Session Leader and Panelist. MAGI Clinical Research vConference.
November 9, 2020.

"How COVID-19 Is Changing Clinical Trial Agreements."
MAGI Clinical Research Cloud Conference 2020.
July 2, 2020.

"CTAs for Investigator-Initiated Trials."
Session Chair. MAGI Clinical Research Cloud Conference 2020.
June 22, 2020.

"Negotiating Clinical Trial Agreements: Balancing the Interests of Sponsors and Healthcare Providers".
Strafford Publications.
April 28, 2020.

"Medical Device Development – From Conception to Market Success" (Panelist).
Licensing Executives Society Philadelphia Chapter Meeting.
July 13, 2016.

"The Clinical Trials Contracting Process: Resolve Negotiating and Compliance Stumbling Blocks to Get the Sites Up and Running!"
Thompson Information Services. November 3, 2015;
October 1, 2014.

"Introduction to the Clinical Trials Contracting Process – Primarily from the Sponsor's Perspective".
20th Annual Health Law Institute of the Pennsylvania Bar Institute.
March 13, 2014.

"Clinical Trial Agreements and Minimization of Contract, Regulatory, and Business Risk – Primarily from the Sponsor's Perspective."
19th Annual Health Law Institute of the Pennsylvania Bar Institute.
March 13, 2013.

"Clinical Trial Agreements and Minimization of Legal, Regulatory and Business Risk – Primarily from the Sponsor's Perspective."
BioWorld (Part of Thompson Media Group).
October 16, 2012.

"Clinical Trial Agreements and Minimization of Risk."
Philadelphia Bar Association Health Care Law Committee Meeting.
April 26, 2012.

"Clinical Research Practices that Minimize Risk."
Hogan Lovells Life Sciences Seminar Series.
September 13, 2011.

"Negotiating Clinical Trial Agreements: Lessons Learned by Sponsors of Multi-Center Trials."
Thompson Interactive Audio Conference.
July 14, 2011.

"Negotiating Clinical Trial Agreements: Strategies to Protect Your Business Interests."
Thompson Interactive Audio Conference.
December 9, 2010; December 11, 2008; July 10, 2008.

"Negotiating Clinical Trial Agreements for Sponsors: Don't Just Trust Your Template."
Elsevier Business Intelligence Webinar.
July 22, 2010.

"Legal, Regulatory and Business Issues Faced by Parties Negotiating Clinical Trial Agreements."
12th Annual Health Law Institute of the Pennsylvania Bar Institute.
March 16, 2006.

"Drafting and Negotiating Web and Other Internet-Related Agreements."
Advanced Computer Law Institute at Georgetown University Law Center, Washington, D.C.
March 12, 1999.

publications

"FDA Issues Final Guidance on Electronic Source Data in Clinical Trials"
20th Annual Health Law Institute, Pennsylvania Bar Institute, Vol. 1, Ch. Q,
March 2014.

"Sunshine Comes to Clinical Trials: Sponsors, CROs, Physicians and Teaching Hospitals Need to Prepare for Federal Financial Disclosure"
Regulatory Focus, Regulatory Affairs ProfessionalsSociety (RAPS),
February 1, 2012.

"FDA Issues Draft Guidance on Financial Disclosure by Clinical Investigators"
Regulatory Focus, Regulatory Affairs Professionals Society,
July 6, 2011.

"FDA's Financial Disclosure Regulations: careful compliance in a changing landscape – Part II"
Regulatory Focus, Regulatory Affairs Professional Society,
December 27, 2010.

"FDA's Financial Disclosure Regulations: careful compliance in a changing landscape – Part I"
Regulatory Focus, Regulatory Affairs Professional Society,
November 15, 2010.

"How Discreet is Your Data?"
Good Clinical Practice Journal,
July 1, 2007.

"Guarding Against Conflict"
Good Clinical Practice Journal,
June 1, 2007.

"The Business of Contracting with Clinical Sites"
Good Clinical Practice Journal,
May 1, 2007.

"Negotiating Clinical Trial Agreements"
RAJ (Regulatory Affairs Journal) Devices, Sept/Oct. 2006, and RAJ Pharma,
July 2006.

"The Business of Clinical Trials Part 2: Finance and Risk Allocation"
Medical Device & Diagnostic Industry,
October 2005.

"The Business of Clinical Trials, Part 1: Negotiating Confidentiality, Intellectual Property and Publications"
Medical Device & Diagnostic Industry,
September 2005.

"Preparing a Company's Web Site for a Legal Audit"
The Computer Lawyer, Vol. 16, No. 6/7,
June – July 1999.

fun facts

Favorite high energy activities: skiing, swimming (preferably ocean), hiking, tennis

Favorite quiet activities: reading, QiGong

Favorite kitchen activities: baking, letting caged bunny out to do zoomies, not cooking

Favorite reading: science fiction, magical realism, Eastern philosophy

Favorite TV shows: Lost, The Expanse, South Park, Person of Interest, The Good Place

Favorite Sci Fi technology that needs to be invented: transporter