



## Katherine Leibowitz

Co-Founder and Managing Member

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### biography

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For almost 30 years, clients have relied on Katherine for her practical and incisive contracts and counseling in life sciences and technology. She has deep experience in the clinical trials enterprise and technology commercialization.

Katherine began her legal career as a technology lawyer in Northern Virginia at Hogan Lovells, a Top 10 global law firm. During the Dot Com boom, Katherine quickly established herself as the “go-to person” for Internet, web site and ecommerce contracts and counseling. Katherine was the first lawyer in the office to have desktop access to the Internet (after submitting a request on paper).

Moving to Hogan Lovells’ Philadelphia office opened the door to life sciences and medical technology opportunities. There, Katherine expanded her knowledge to FDA regulatory, HIPAA, human subject protection, fraud and abuse, reimbursement, international data protection and litigation risk management. She learned (and in many cases, spearheaded the development of) all the ins and outs of drafting clinical trial contracts and counseling clients in matters relating to clinical trials operations.

In 2013, she and her husband, Steve, decided to start their own firm dedicated to making life sciences contracting easier and more accessible for small to middle-sized companies and institutions. A seasoned life sciences regulatory and technology lawyer, Katherine provides a full range of services from templates tailored to her clients’ needs to markups of contracts prepared by the other side, to complex negotiations and sophisticated counseling.

Katherine is passionate about helping her clients save lives and improve patient health – and is determined to make a big impact by empowering life sciences companies and institutions.

## education

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**J.D., University of Pennsylvania Law School**

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

## memberships

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**Board of Directors, The Gateway School**

**American Bar Association**

**Philadelphia Bar Association Health Law Committee**

**Women Owned Law**

## bar admissions

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**Pennsylvania**

## presentations

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**"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

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"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 Professionals Society (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

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**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