Mark Barnes

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Practice

Mark Barnes—named the 2019 *Financial Times* "Legal Innovator of the Year"—is a preeminent thinker and adviser to health care and life sciences companies, academic institutions and investors. He has extensive experience guiding clients on legal issues related to research with humans and animals, stem cell and genetic research, research grants and contracts, research misconduct, international research collaborations and "foreign influence" regulations, and data privacy. Using his background as a former senior official in the New York City and New York State Departments of Health in the 1980s and early 1990s, Mark has been assisting academic and industry clients to navigate critical legal issues related to the COVID-19 pandemic, including developing workplace policies in line with public health guidance and clinical trial guidelines in the context of the pandemic.

Throughout his career, Mark has played a leadership role in the areas of clinical trials and data privacy. Since the late 1990s and to the present, Mark has served, first as a member and later as a subcommittee chair, of the HHS Secretary's Advisory Committee on Human Subjects Protections (SACHRP), formerly known as the HHS National Human Research Protections Advisory Committee (NHRPAC). In 2012, with Dr. Barbara Bierer, Mark started, and continues to serve as faculty co-chair of, the Multi-Regional Clinical Trials Center of Harvard University and Brigham and Women's Hospital (MRCT Center), a project designed to improve the planning, conduct and regulation of multi-national clinical trials, with a special emphasis on trials in the emerging economies. Much recent effort of MRCT Center, which Mark has led, has been devoted to clarifying the secondary research uses of personal data under the jurisdiction of the EU General Data Privacy Regulation (GDPR), about which Mark has published extensively. Mark is a co-founder and board member of Vivli, a nonprofit that collects and shares participant-level anonymized data from clinical trials conducted by life sciences companies, hospitals and academic research institutions. Vivli is currently creating a special COVID-19 platform to allow for use in COVID-related data research.

Mark served as the executive vice-president of St. Jude Children's Research Hospital, where, in 2005-6, he established a vaccine study center in the Eastern Highlands of Zimbabwe, in collaboration with Africa University. At

Education

- LLM, Columbia University School of Law, 1991
- JD, Yale Law School, 1984
- BA, Bennington College, 1981

Bar Admissions

- Massachusetts, 2013
- New York, 1986
- Connecticut, 1985

Harvard University, Mark was the university-wide senior research officer and associate provost for research, and from 2008 to 2015 taught health care law and public health law at the Harvard Law School. During a period of regulatory crisis in 2012, Mark was the acting director of the Harvard Primate Center.

Mark has particular experience in establishing legal structures and operational plans for international service and research projects, especially in emerging economies, and he served as the first executive director of Harvard's extensive PEPFAR-funded AIDS treatment programs in Nigeria, Tanzania and Botswana, later chairing the Harvard oversight committee for that project. At Harvard, he worked with faculty from across the University to establish service, demonstration and research projects throughout the world, including China, Viet Nam, Colombia, Peru, and the Gulf States, among other countries. From 2018 until the present, Mark has represented a number of universities and academic medical centers in allegations of "foreign influence" and academic espionage by faculty and post-doctoral fellows.

Since 1986, Mark has taught at a number of law schools, including Columbia, NYU, Harvard, and Yale. The subjects he has covered include health care law and finance, public health law, the law of human subjects research, occupational safety and health law, and managed care law. Since 2014, at Yale Law School, he has taught health care law and finance, public health law, and the law of biomedical research and is an affiliated faculty of the YLS Solomon Center for Health Law and Policy.

Mark's diverse professional background includes senior policy and administrative positions at the New York State Department of Health and the New York City Department of Health, where, among other duties, he directed the Ryan White CARE Act program providing medical, substance abuse and mental health treatment to New Yorkers living with HIV/AIDS. and in 1993, was a senior legal advisor to the health reform efforts at the Clinton White House. Mark was president of the New York State Bar Association Health Law Section (2007-2008).

Awards

- *Financial Times,* Legal Innovator of the Year (2019)
- *The National Law Journal,* Trailblazer (2019-2020)
- *Inspiring Yale Award for the Yale Law School* (2018)
- *Legal 500* (2015, 2017-2018)
- *New York Super Lawyers* (2006-2008)
- *The Best Lawyers in America* (1997-2022)
- *Chambers USA: America's Leading Lawyers for Business* (2004-2006)
- *Thurgood Marshall Award for Death Penalty Advocacy, Association of the Bar of the City of New York*

Publications

- Co-author, “Demystifying Schrems II for the Cross-Border Transfer of Clinical Research Data,” *Journal of Law and the Biosciences* (October 23, 2021)
- Quoted, “Everything We Know About Workplace Vaccine Mandates,” *New York Magazine’s The Cut* (September 28, 2021)
- Quoted, “Biden Vaccine Plan for Employers Raises Longstanding Legal Questions Over Mandates, Experts Say,” *USA Today* (September 10, 2021)
- Quoted, “Biden Vaccine Mandate Should Withstand Legal Challenges, Experts Say,” *Barron’s* (September 9, 2021)
- Quoted, “Panel Offers Strategies to Ensure Privacy in Research Recruitment,” *Report on Patient Privacy* (August 2021)
- Quoted, “HHS: Conti Takes Ransomware to New Level,” *Report on Patient Privacy* (August 2021)
- Featured, “Until Proven Safe: The History and Future of Quarantine,” Macmillan Publishers (July 2021)
- Quoted, “Boosting Vaccinations,“ *The New York Times* (July 23, 2021)
- Quoted, “Hospital Vaccine Mandates Suggest Success in Boosting U.S. Shots,” *Bloomberg News* (July 9, 2021)
- Quoted, “SACHRP: Thorny Sponsor Interactions With Subjects Require Approval, Oversight,” *Report on Research Compliance* (June 1, 2021)
- Quoted, “When Data Protection Becomes Dangerous,” *Frankfurter Allemeine* (May 9, 2021)
- Quoted, “Medical Research Gets Lift With NIH Veteran as New HHS Attorney,” *Bloomberg Law* (March 22, 2021)
- Co-author, “Ethical Challenges in Clinical Research During the COVID-19 Pandemic,” *Journal of Bioethical Inquiry* (November 9, 2020)
- Co-author, “Ethical and Practical Concerns about IRB Restrictions on the Use of Research Data,” *Ethics & Human Research* (November 2, 2020)
- Co-author, “How to fix the GDPR’s frustration of global biomedical research,” *Science Magazine* (October 2, 2020)
- Quoted, “Ransomware Attack Hits Universal Health Services” *The Wall Street Journal* (September 28, 2020)
- Quoted, “Virus Testing Push Leaves FDA Lab Oversight in ‘a Bizarre Limbo,’” *Bloomberg Law* (August 26, 2020)

- Quoted, “Teachers Sue to Keep Schools Shut as Parents Demand They Reopen,” *Bloomberg News* (July 21, 2020)
- Co-author, “The Research Compliance Landscape Is Evolving Quickly,” *Law360* (June 24, 2020)
- Cited, “New report outlines what's needed to safely return to work,” CNN.com (June 18, 2020)
- Co-author, “Challenges of “Return to Work” in an Ongoing Pandemic,” *The New England Journal of Medicine* “Special Report” (June 18, 2020)
- Quoted, “As workplaces slowly reopen, tech companies smell a new multibillion-dollar opportunity: Helping businesses trace coronavirus,” *CNBC.com* (May 10, 2020)
- Co-author, “6 Ways Lawmakers Could Address COVID-19 Liability For Cos.,” *Law360* (May 1, 2020)
- Co-author, “From Genetics to Genomics: Facing the Liability Implications in Clinical Care,” *The Journal of Law, Medicine & Ethics* (Spring 2020)
- Profiled, “Healthcare Life Sciences Trailblazers 2020,” *The National Law Journal* (April 1, 2020)
- Co-author, “Disruptive and Avoidable: GDPR Challenges to Secondary Research Uses of Data,” Nature publishing’s *European Journal of Human Genetics* (March 2, 2020)
- Co-author, “Science and Security in Federally-Funded Research,” *AHLA Connections Magazine* (March 2020)
- Co-author, “'Foreign Influence' in Research: Science and Security Under the Microscope,” *National Law Journal* and *Law.com* (January 31, 2020)
- Quoted, “Foreign Influence on Science Has DOJ Flexing False Claims Act,” *Bloomberg Law* (December 20, 2019)
- Featured, “Top 10 individuals: winner’s mission to share medical data,” *Financial Times* (December 10, 2019)
- Co-author, “Toward Improving Practices for Submission of Diagnostic Tissue Blocks for National Cancer Institute Clinical Trials,” *American Journal of Clinical Pathology* (October 15, 2019)
- Co-author, “What OIG Self-Disclosure Guidance Means For HHS Grantees,” *Law360* (August 8, 2019)
- Co-author, “Post-Submission Update: The Evolving Regulatory Landscape for Clinical Trials in India,” *Food and Drug Law Journal* (July 2019)
- Co-author, “Expanding Regulatory Oversight of Foreign Influence in NIH-Funded Research,” *Bloomberg Law* (July 23, 2019)
- Co-author, “Implementing Regulatory Broad Consent Under the Revised Common Rule,” *Journal of Law, Medicine & Ethics* (July 12, 2019)

- Co-author, “Guidance Regarding Interaction Between GDPR and EU Clinical Trials Regulation Leaves Several Questions Unanswered,” *Bloomberg Law* (February 14, 2019)
- Profiled, “National Institute of Health’s Research Ethics Committee,” *Global Legal Chronicle* (January 7, 2019)
- Co-author, “Insights On Right To Try Act And 'Expanded Access' Concerns,” *Law360* (December 18, 2018)
- Quoted, “Do As I Say, And As I Do,” *Applied Clinical Trials* (December 1, 2018)
- Quoted, “No-Deal Brexit Will Require New U.S.-U.K. Drug Inspection Pact,” *Bloomberg Law* (December 4, 2018)
- Co-author, “The Evolving Regulatory Landscape for Clinical Trials in India,” Food and Drug Law Institute’s *Food and Drug Law Journal* (December 2018)
- Quoted, “HIV Drugs to Get Speedier Reviews From World Health Organization,” *Bloomberg Law* (November 30, 2018)
- Quoted, “FDA Plans Effort to Lower Costs of Clinical Trials,” *Bloomberg Law Pharmaceutical & Life Sciences* (November 13, 2018)
- Co-author, “The Criticality of the Clinical Trial Enterprise in India,” Organization of Pharmaceutical Producers of India (October 2018)
- Quoted, “California Exempts Clinical Trial Data From Privacy Law,” *Bloomberg Law* (September 24, 2018)
- Co-author, “INSIGHT: The Right to Try Act and Its Implications for Pharmaceutical Manufacturers,” *Bloomberg Law* (July 24, 2018)
- Cited, “Returning Individual Research Results to Participants: Guidance for a New Research Paradigm,” National Academies of Sciences Consensus Study Report (July 2018)
- Co-author, “GDPR Complicates Admissions Applications for U.S. Universities,” Bloomberg BNA’s *Privacy Law Watch* (June 27, 2018)
- Co-author, “Development and Implementation of Participant Safety Plans for International Research with Stigmatized Populations,” *The Lancet* (June 24, 2018)
- Co-author, “Will Consent Be Disfavored as Basis for Processing Personal Data in Clinical Research Under EU Data Protection Law?” Bloomberg Law’s *Medical Law & Research Policy Report* (June 15, 2018)
- Quoted, “EU’s new data-privacy rule will be felt by many Americans, too,” *The Boston Globe* (May 23, 2018)
- Quoted, “FDA’s Regulatory Agenda Sheds Light on Research Rule Changes,” *Bloomberg Law* (May 11, 2018)

- Quoted, "HHS Advisers Urge Talks with EU to Avoid Regulatory Clash under Upcoming Data Rules," *Inside Cybersecurity* (May 3, 2018)
- Co-author, "Final Guidelines on Consent Requirements Under the EU General Data Protection Regulation: Implications for Scientific Research," Bloomberg BNA's *Life Sciences Law & Industry Report* (April 30, 2018)
- Co-author, "India Releases New Draft Rules Reinforcing Compensation Requirements for Injuries 'Related To' Clinical Trials," Bloomberg BNA's *Life Sciences Law & Industry Report* (April 2, 2018)
- Quoted, "Everyone Was Quite Upset by HHS Mandate for Virtual SACHRP Meetings to Save Money," *Report on Research Compliance* (April 2018)
- Quoted, "Online forums give investors an early warning of shady scientific findings," *STAT* (January 30, 2018)
- Quoted, "Human CRISPR Trials Set to Get Underway, with Patents Pending," *The CenterWatch Weekly* (January 29, 2018)
- Quoted, "HHS Delays Major Research Regulation Effective Date," Bloomberg BNA's *Health Care Daily Report* (January 18, 2018)
- Co-author, "New Draft Guidelines on GDPR Consent Requirement's Application to Scientific Research," Bloomberg BNA's *Medical Law & Research Policy Report* (January 17, 2018)
- Quoted, "Human Research Rule Moves Closer to One-Year Delay," Bloomberg BNA's *Health Care Daily Report* (January 8, 2018)
- Quoted, "Is HHS Research Oversight Office Enforcement In Decline?," Bloomberg BNA's *Medical Research Law & Policy Report* (December 6, 2017)
- Co-author, "FDA Eases Burdens on Expanded Access Use," Bloomberg BNA's *Medical Research Law & Policy Report* (November 15, 2017)
- Co-author, "Extraterritorial Effect of the GDPR and Implications for U.S. Academic Medical Centers Treating EU Patients," Bloomberg BNA's *Medical Law & Research Policy Report* (November 1, 2017)
- Quoted, "Proposed Delay to Research Rule Still Up in the Air," Bloomberg BNA's *Medical Devices Law & Industry Report* (October 19, 2017)
- Co-author, "Certificates of Confidentiality After the 21st Century Cures Act" Bloomberg BNA's *Medical Research Law and Policy Report* (October 4, 2017)
- Quoted, "Acting HHS Chief Faces Decisions on Insurance, Research Programs," Bloomberg BNA's *Health Care Daily Report* (October 3, 2017)
- Quoted, "Comments Wanted on Plan to Open Up Genomic Study Data," Bloomberg BNA's *Health IT Law & Industry Report* (September 29, 2017)
- Co-author, "Differences in health-related quality of life between HIV-positive and HIV-negative people in Zambia and South Africa: a cross-

sectional baseline survey of the HPTN 071 (PopART) trial," *The Lancet* (September 27, 2017)

- Co-author, "Reconciling Personal Data Consent Practices in Clinical Trials with the EU General Data Protection Regulation," Bloomberg BNA's *Medical Research Law & Policy Report* (September 20, 2017)
- Quoted, "Herpes Vaccine Trial in St. Kitts Likely Didn't Follow FDA Regs," Bloomberg BNA's *Medical Research Law & Policy Report* (September 6, 2017)
- Co-author, "SACHRP Releases Guidance on Broad Consent Under Revised Common Rule," Bloomberg BNA's *Life Sciences Law & Industry Report* (September 15, 2017)
- Co-author, "What to Know About New FDA Informed Consent Guidance," *Law360* (August 11, 2017)
- Co-author, "A Modern Approach to Digital Health Product Regulation," *Law360* (August 4, 2017)
- Quoted, "Human Research Office Needs More Independence, Transparency," Bloomberg BNA's *Health Care Fraud Report* (August 3, 2017)
- Quoted, "HHS Research Advisory Panel Clarifies 'Broad Consent, '" Bloomberg BNA's *Health IT Law & Industry Report* (July 28, 2017)
- Quoted, "Case Law, Regulations Don't Support Individual's Biospecimen Ownership," Bloomberg BNA's *Medical Research Law & Policy Report* (June 21, 2017)
- Quoted, "Streamlining FDA Alzheimer's Drug Approval Gains Support," Bloomberg BNA's *Medical Research Law & Policy Report* (June 7, 2017)
- Quoted, "HHS Research Advisers Mull How to Get Broad Consent for Future Studies," Bloomberg BNA's *Medical Research Law & Policy Report* (June 7, 2017)
- Quoted, "Public Disclosure of Clinical Trial Info Gets Global Push," Bloomberg BNA's *Medical Research Law & Policy Report* (June 7, 2017)
- Co-author, "Revised 'Common Rule' Shapes Protections for Research Participants," *Health Affairs* (May 2, 2017)
- Co-author, "Using Biospecimens Collected Abroad in Future Research: Key Considerations," Bloomberg BNA's *Medical Research Law & Policy Report* (April 19, 2017)
- Quoted, "Will Trump's Budget Pull Back on Repaying Indirect Research Costs?" Bloomberg BNA's *Medical Research Law & Policy Report* (April 5, 2017)
- Quoted, "Battered Biotech's Breach claims for Nanotech Patent License Denied," Bloomberg BNA's *Medical Research Law & Policy Report* (April 5, 2017)

- Quoted, "Will 'One-in, Two-Out' Order Hamper FDA's Clinical Trial Regulations," Bloomberg BNA's *Medical Research Law & Policy Report* (March 15, 2017)
- Co-author, "Recent Changes in French Law Affecting Clinical Research and Trials," Bloomberg BNA *Medical Research Law & Policy Report* (February 15, 2017)
- Co-author, "HHS Finalizes Comprehensive Revisions to the Common Rule," Bloomberg BNA *Life Sciences Law & Industry Report* (January 26, 2017)
- Quoted, "White House Finalizes Scaled Back Research Regs," *Health Care Daily Report* (January 18, 2017)
- Co-author, "21st Century Cures Act: Broad Revisions to the Federal Regulation of Medical Research," Bloomberg BNA *Medical Research Law & Policy Report* (January 18, 2017)
- Quoted, "Obama Administration Still Wants to Release New Common Rule," *Life Sciences Law & Industry Report* (November 18, 2016)
- Quoted, "Drug Industry May Face Less Scrutiny Under Trump," *Health Care Daily Report* (November 10, 2016)
- Quoted, "Clinical Trials: New Clinical Trial Reporting Rule, Policy Toughen Enforcement," Bloomberg BNA's *Medical Research Law & Policy Report* (September 19, 2016)
- Quoted, "Informed Consent: Court Dismisses Guatemala VD Study Suit, But Allows Refiling," Bloomberg BNA's *Medical Research Law & Policy Report* (September 13, 2016)
- Co-author, "A Global, Neutral Platform for Sharing Trial Data," *The New England Journal of Medicine* (May 11, 2016)
- Quoted, "FDA Cleans Up IRB Regulatory Language for Noncompliance," Bloomberg BNA *Medical Research Law & Policy Report* (April 4, 2016)
- Co-author, "Federal Research Regulations for the 21st Century," *The New England Journal of Medicine* (March 31, 2016)
- Co-author, "Impact of the European Union's Approved General Data Protection Regulation On Scientific Research and Secondary Uses of Personal Data," Bloomberg BNA *Medical Research Law & Policy Report* (Feb. 17, 2016)
- Co-author, "Corruption Risks in International Clinical Trials: Navigating Between Anti-Bribery Laws and Local Circumstances," Bloomberg *BNA Medical Research Law & Policy Report* (Jan. 6, 2015)
- Co-author, "The CLIA/HIPAA Conundrum of Returning Test Results to Research Participants," Bloomberg BNA *Medical Research Law & Policy Report* (July 15, 2015)

- Co-author, “India’s Proposed Amendments to the Drug and Cosmetics Act: Compensation for Injuries to Clinical Trial participants and the Criminalization of Clinical Research,” Bloomberg BNA *Life Sciences Law & Industry Report* (January 23, 2015)
- Quoted, “Indian Regulators Propose Draft Legislation with New Penalties for Clinical Trials,” FDANews’ *Drug Industry Daily* (January 6, 2015)
- Co-author, “National Institutes of Health Issues a Notice of Proposed Rulemaking on Clinical Trials Registration and a Draft Policy on Registration and Reporting of Results for NIH-Funded Clinical Trials,” Bloomberg BNA’s *Medical Law & Policy Research Report* (December 2014)
- Co-author, “Reviewing HIV-Related Research in Emerging Economies: The Role of Government Reviewing Agencies,” Developing World Bioethics (December 2014)
- Co-Author, “Impact of Proposed Federal Research Regulation Amendments (the Common Rule NPRM) on Life Sciences Companies,” Bloomberg BNA *Life Sciences Law & Industry Report* (November 13, 2015)
- Quoted,” India Creates Expert Panel to Review Drug Application Forms, Procedures,” *International Pharmaceutical Regulatory Monitor* (November 12, 2014)
- Quoted, “Edits to ethics code rankle,” *Nature* (November 11, 2014)
- New EU Clinical Trials Regulation and its Interaction With Proposed EU Privacy Regulation and Proposed EMA Policy on Clinical Trials Data Transparency,” *Bloomberg BNA Medical Research Law & Policy Report* (August 20, 2014)
- Quoted, “Alternatives to GCP Standards Said Needed To Ensure Trial Quality in Emerging Markets,” Bloomberg BNA (September 5, 2013)
- Co-author, "EMA Draft Policy on Publication and Access to Clinical Trials Data Provides Broad Researcher Access to Participant-Level Data," *Bloomberg BNA Medical Research Law & Policy Report* (July 17, 2013)
- Co-author, “HIPAA Final Rule Clarifies Major Research Issues,” Bloomberg BNA’s Medical Research Law & Policy Report (February 6, 2013)
- Co-author, “European Union Negotiations Reach Agreement on New Clinical Trials Regulation,” Bloomberg BNA's Medical Research Law & Policy Report (February 5, 2014)
- Mark Barnes and Sarah Blumenthal, "Implications of the Federal Physician Payments Sunshine Act for Clinical Research," *Bloomberg BNA Medical Research Law & Policy Report* (November 21, 2012)
- Quoted, “Anti-Health Reform Measures DOA After High Court Ruling,” Health Care *Law360* (November 7, 2012)

- Co-author, "Proposed Revisions to the Federal Common Rule: Implications for the Role of the IRB in Institutional Oversight Programs," *Bloomberg Health Law Rep.* (February 6, 2012)
- Co-author, "Protecting Research Participants While Reducing Regulatory Burdens," *306 JAMA 2260* (November 23-30, 2011)
- Co-author, "The Obligation to Provide Antiretroviral Treatment in HIV Prevention Trials," *21 AIDS 1229-1231* (2007)
- Co-author, "Informed Consent: FDA Draft Guidance on Emergency Research,"*BNA Med. Research Law & Pol'y Rep. 634* (September 20, 2006)
- Co-author, "*Washington University v. Catalona*: Ownership and Use of Human Biologic Materials Collected for Research," *BNA Med. Research Law & Pol'y Rep.* (May 3, 2006)
- "HIPAA and Commercial Clinical Research," *Good Clinical Practice: A Question and Answer Reference Guide* (May 2006)
- Co-author, "Clinical Trials in 2006: Trial Registration, International Research, Research Billing, Adverse Events, and Secondary Uses of Data and Tissue," *BNA Med. Research Law & Pol'y Rep. 26* (January 1, 2006)

Presentations

- Presenter, keynote address on "Navigating the Pandemic Research Landscape, Legal and Regulatory Perspectives," The Feinstein Institutes for Medical Research at Northwell Health Virtual Conference (April 15, 2021)
- Presenter, keynote address on "Overcoming Legal Obstacles and Improving the Law of Genomics," LawSeq: Facing the Legal Barriers to Genomic Research & Precision Medicine Conference, Ropes & Gray, Boston, MA (December 2, 2020)
- Presenter, "MRCT Center 2019 Annual Meeting," Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard, Cambridge, MA (December 4, 2019)
- Presenter, "Challenges for Health Research Arising From the GDPR," ISC Intelligence in Science, Brussels, Belgium (November 19, 2019)
- Speaker, "Law and Policy of Artificial Intelligence, Robotics and Telemedicine in Healthcare," Yale Law School Solomon Center for Health Law and Policy (November 2, 2018)
- Speaker, "Complying With the EU GDPR Requirements in Clinical Trials," Ropes & Gray Roundtable Discussion (December 2017)
- Speaker, "Global Regulatory Development and Enforcement," Berkley Research Group conference on Regulatory Action in India's Pharmaceutical and Medical Device Industry (October 26, 2017)