BARBARA J. EVANS
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I. EDUCATION

Legal Education
J.D., Yale Law School, 1994
LL.M. Health Law, University of Houston, 2003
Admitted to practice: New York (since 1996), Texas (since 2000)

Other Education
Post-doctoral Fellow, Clinical Ethics, M.D. Anderson Cancer Center, 2003 – 2004
Ph.D., Earth Sciences, Stanford University, 1984
M.S., Applied Earth Sciences, Stanford University, 1982
B.S., Electrical Engineering, with Honors, University of Texas at Austin, 1979

II. CURRENT EMPLOYMENT

University of Florida, Gainesville, FL. Professor of Law and Stephen C. O'Connell Chair, Fredric G. Levin College of Law; Professor of Engineering, Herbert Wertheim College of Engineering (2020 – present) and Glenn and Deborah Renwick Faculty Fellow in AI and Ethics, Herbert Wertheim College of Engineering (2023 – present); Associate Director for AI Alignment, Intelligent Clinical Care Center, University of Florida College of Medicine (2024 – present)

Classes Taught. Law courses: Torts, Health Law Survey, Biotechnology & Medical AI Policy. Engineering course: EGN 6933/Bio1 (Medical AI)

Research interests. Legal and ethical issues with artificial intelligence/machine learning clinical decision support (CDS) software. Data privacy. Financing, governance, and access to data for large-scale medical data commons to support research, public health, and clinical health care. Rights of people whose data are stored in medical and genomic databases. Legal, regulatory, and ethical concerns with gene-editing technologies and genomic and other diagnostic tests. Food & Drug Administration (FDA) and Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulatory issues, especially for medical devices and medical software tools. Health care law.

Sponsored research projects. See Section IV, pages 3 - 6
Professional Recognition and Awards. See Section V, page 6
Service to Levin College of Law. See Section VI.A, page 6
Service to University of Florida. See Section VI.B, page 7
Professional and Federal Advisory Committee Service. See Section VI.C, pages 7 - 10
Publications. See Section VII, pages 11 - 26
Presentations. See Section VIII, pages 26 - 46

III. PRIOR EMPLOYMENT

2007 – 2020 **University of Houston**, Houston, TX
University of Houston Law Center (2007-2020), Mary Ann and Lawrence E. Faust Professor of Law (2018-2020) and Director, Center for Biotechnology & Law (2007-2020), Alumnae College Professor of Law (2016-2018); George Butler Research Professor (2014-2016); Professor of Law (9/2011-present); Associate Professor (1/2007-8/2011); Co-director, Health Law & Policy Institute (2007-2013).
University of Houston Cullen College of Engineering (2017-2020), Professor of Electrical and Computer Engineering (2017-2020).
Other affiliations within the Texas Medical Center. Center for Medical Ethics and Health Policy, Baylor College of Medicine, Health Policy Scholar (2016-2020), Affiliated Member (2013-present).

Courses taught. U.S. Biotechnology Regulatory Framework; Regulating Disruptive Innovation; Medical Devices Law, Regulation, and Ethics (for Electrical and Computer Engineers); Hot Topics in FDA Law; Biotechnology and the Law; Health Industry Basics: Providers-Innovators-Regulators; Law and Genetics; Healthcare Access, Regulation, and Enterprise; Healthcare Finance, Organization, and Quality; and Torts.

2004 – 2007 **Indiana University**, Indianapolis, IN
Director, Program in Pharmacogenomics, Ethics, and Public Policy, Indiana University School of Medicine/Center for Bioethics (9/2004-5/2007, 50% commitment); **Senior Scientist** (9/2004-8/2006), then **Research Professor of Medicine** (9/2006-5/2007), **Indiana University Department of Medicine/Division of Clinical Pharmacology; Adjunct Professor of Law** (9/2004-8/2006), **Visiting Professor of Law** (8/2006-12/2006, 50% commitment to law school) **Indiana University School of Law (Indianapolis). Courses taught**. Administrative Law; Law and Genetics

2004 – 2006 **Counsel, Medical Technology Practice Group, Baker & Daniels, L.L.P.,** Indianapolis (part-time commitment, 2004-2006, when our practice group moved to Epstein, Becker & Green); **Counsel, Health and Life Sciences Practice, Epstein, Becker & Green, P.C.,** Washington, D.C (part-time commitment, 1/2006-9/2006)

2003 – 2004 **The University of Texas M.D. Anderson Cancer Center**, Houston, TX
Post-doctoral Fellow in Clinical Ethics (9/2003-6/2004)

1996 – 2002 **LeBoeuf, Lamb, Greene & MacRae, L.L.P.,** New York and Moscow
Associate (5/1996-5/1998); **Partner** (6/1998-7/2001); **Of Counsel** (8/2001-2/2002). Advised U.S., U.K., and Russian corporations on regulatory and transactional matters, including major infrastructure asset acquisitions and regulatory compliance. Advised governments on major legal reform projects

in the energy and infrastructure sectors as a prelude to privatization. Supervised the legal team for the World Bank-funded Russian Federation Electricity Sector Reform Support Project (Project 643/02/98 PDL–101) and, as subcontractor to Andersen Consulting, acted as regulatory advisor to the Kres Commission which President Putin appointed in 2000 to implement reforms in Russia's electric power sector.

1994 – 1996 **International Bank for Reconstruction and Development (The World Bank),** Washington, D.C., **Senior Energy Economist, Region IV Europe and Central Asia, Infrastructure Division** (9/1994 – 3/1996). Served as project manager or economist on World Bank lending projects to modernize energy infrastructure, address environmental problems related to the Chernobyl accident, and provide sectoral and macroeconomic support in Region IV nations of the former Soviet Union.

1992 – 1994 **Part-time and Temporary Employment While in Yale Law School Economist**, John F. Kennedy School of Government, Harvard University, Project for Economic Reform in Ukraine, Kiev, Ukraine (full-time, 6/1992-8/1992). **Regulatory Consultant** under Contract No. MG498, International Bank for Reconstruction and Development (The World Bank), Washington, D.C.; Kiev, Ukraine; Vilnius, Lithuania; and Kishinov, Moldova, (part-time, 10/1992-8/1994). **Regulatory Consultant** under Contract No. C4220, The European Bank for Reconstruction and Development, London and Kiev, Ukraine (one short project in 1993-1994). **Summer Associate and Consulting Economist,** LeBoeuf, Lamb, Greene & MacRae, L.L.P., New York and Moscow (full-time, 6/1993-8/1993; part-time, 9/1993-1/1994).

Before law school – I held various positions as an engineer and economist in the energy industry. Details available on request.

IV. GRANTS AND SPONSORED RESEARCH PROJECTS (AWARDED OR COMPLETED)

Co-Investigator, **Artificial Intelligence Passport for Biomedical Research (AIPassportBMR): Digital Experiential Learning Community for Upskilling in Artificial Intelligence for Biomedical, Behavioral, and Clinical Research.** NIH/NIGMS GM155478 (Azra Bihorac, PI), Sponsored by National Institutes of Health, Federal (9/1/2024 – 8/31/2029)

Legal studies lead, Ethical and Trustworthy AI (ETAI) pillar, National Institutes of Health Common Fund's Bridge2AI **Patient-Focused Collaborative Hospital Repository Uniting Standards (CHoRUS) for Equitable AI.** NIH OT2OD0327 (9/1/2022-8/31/2026) (Eric S. Rosenthal, PI, Azra Bihorac, UF site PI). (Effective 2024, NIH renamed this project, "**Bridge2AI Program in Clinical Care AI through the CHoRUS Network"** to reflect an expansion of scope beyond critical care and including clinical health care more generally)

Member, Ethics Advisory Panel, **Engineering Research Center for Advanced Technologies for the Preservation of Biological Systems (ATP-Bio).** NSF EEC-1941543 (2020-2025) (John Bischof et al., PIs)

Member, Ethics Working Group, **Highly Portable and Cloud-Enabled Neuroimaging Research: Confronting Ethics Challenges in Field Research with New Populations**. NIH1RF1MH123698 (8/7/2020-8/6/2024) (Frances Lawrenz, Francis Shen, and Susan M. Wolf, PIs)

Member, Bioethics Advisory Panel, **Collaborative Research: Booting up a Mirror Cell.** NSF EF 1935372 (9/1/2019-8/31/2023) (Neal Devaraj, PI)

Data Privacy Consultant, **The Genetic Architecture of Human Facial Morphology** (Bioethics Supplement) NIDCR/NIH OD 3R01DE027023-04S1 (7/1/2020 – 7/30/2021) (Weinberg, Claes, and Wagner (PIs))

Member and regulatory/ethics consultant (through 8/2020), **Industry-University Collaborative Research Center for Building Reliable Advances and Innovations in Neurotechnology (BRAIN)**. National Science Foundation CNS-1650536 (3/2017-5/2020) (Jose Contreras-Vidal & Marco Santelli, PIs)

Legal Working Group Member, **Development of Recommendations and Policies for Genetic Variant Reclassification.** NIH/NHGRI R01HG010365 (Wendy Chung, M.D., Ph.D., and Paul Appelbaum M.D., P.I.s) (12/1/2018-11/30/2022)

Member, Working Group, **Choice of Law in Precision Medicine Research,** NIH/NHGRI (Leslie Wolf and Laura Beskow, PIs) (2020-2021)

Privacy Working Group Member and Co-lead, Data Quality Working Group, **LawSeq^{SM}: Building a Sound Legal Foundation for Translating Genomics into Clinical Application**. NHGRI/NCI 1R01HG008605 (Susan M. Wolf, Ellen W. Clayton, Frances Lawrenz, PIs) (06/06/2016-5/31/2019)

Sentinel System (FDA-14-RFP-1127332). Member of Privacy Panel for Harvard Pilgrim-led consortium to operate the U.S. Food & Drug Administration's Sentinel System, a very large-scale distributed pharmacoepidemiological data network. Subcontract between University of Houston (Barbara J. Evans, P.I.) and Harvard Pilgrim Health Care Institute (Richard Platt, M.D., P.I.) (2014-2019)

Member, Working Group, **Addressing ELSI Issues in Unregulated Health Research Using Mobile Devices**. National Cancer Institute/National Human Genome Research Institute/Office of Science Policy and Office of Behavioral and Social Sciences Research, Office of the Director, National Institutes of Health Project 1R01CA207538 (Mark Rothstein and John Wilbanks, PIs)

Advisory Committee Member, **Building the Medical Information Commons: Participant Engagement and Policy.** NIH/NHGRI R01-HG008918 (Amy McGuire & Robert Cook-Deegan, PIs) (9/14/2015-6/30/2018)

Governance Development for FDA-Harvard Catalyst Activities. Subcontract between University of Houston (Barbara J. Evans, P.I.) and Harvard Pilgrim/Harvard Catalyst for studies under agreement between Sentinel Coordinating Center and U.S. Food and Drug

Administration (HHS223201400030I), for legal research on privacy and human-subject protection issues in public health uses of FDA's Sentinel System (2017-2018)

Clinical Sequencing in Cancer: Clinical, Ethical, and Technological Studies. NIH U01HG006507 (GPJ). Study of CLIA and HIPAA regulatory issues and First Amendment questions surrounding clinical investigators' disclosure of experimental genetic test results to persons participating in research. Subcontract between University of Houston (Barbara J. Evans, P.I.) and the University of Washington (Gail P. Jarvik, P.I.) (2011-2017)

Regulation of Gene-editing Technologies. National Academy of Sciences NAS Agreement 2000006701 (Barbara J. Evans, PI) (2016). Commissioned paper on national regulatory frameworks for human gene editing

Clinical Sequencing Exploratory Research (CSER) Centralized Support Coordinating Center - HIPAA-CLIA Supplement. NIH 3U01HG007307-02S2. Study of impacts genomic testing laboratories will experience after 2014 changes to the individual data access requirements of the HIPAA Privacy Rule. Subcontract between University of Houston (Barbara J. Evans, P.I.) and the University of Washington (Gail P. Jarvik, P.I.) (8/1/2014-3/31/2015)

Consultant, **Clinical Integration of Whole Genome Sequencing: A Policy Analysis**, NIH/NHGRI R01-HG006460-03 (Amy McGuire, P.I.) (2015)

Collaborator, **Thematic Study of Research with Biospecimens**, funded by the National Human Genome Research Institute with co-sponsorship of Case Western Research University and the Petrie-Flom Center at Harvard Law School (I. Glenn Cohen, Barbara Bierer, Suzanne Rivera, Holly Fernandez Lynch, co-PIs) (2015)

Commissioned Paper, **Ownership of Data from Mobile and Wearable Health Devices**, for Robert Wood Johnson Foundation Health Data Exploration Project (Kevin Patrick, M.D., M.S. P.I.) (5/2015-5/2016)

Member of Multidisciplinary Panel, **Reframing Consent for Research**, funded by The Greenwall Foundation (Scott Kim, M.D., Ph.D., David Wendler and Neal Dickert, M.D., Ph.D. co-PIs) (2015)

Greenwall Foundation Faculty Scholar in Bioethics. Funding for study entitled *Governance Models to Enhance the Legitimacy and Public Acceptability of Decisions to Allow Nonconsensual Use of Data Held in Large Health Data Networks* (Barbara J. Evans, P.I.) (7/1/2010-6/30/2013)

Mini-Sentinel II. Collaborative study by Harvard Pilgrim Healthcare Institute and the U.S. Food & Drug Administration/Duke Clinical Trials Transformation Initiative to examine randomization techniques in a very large-scale health data network. Subcontract between University of Houston (Barbara J. Evans, P.I.) and Harvard Pilgrim Health Care Institute (Richard Platt, M.D., P.I.) (2013-2014)

Mini-Sentinel Privacy Panel Project. Subcontract between University of Houston (Barbara J. Evans, P.I.) and Harvard Pilgrim Health Care Institute as prime contractor under Department of Health & Human Services Contract No HHSF2232009100061 (Richard Platt, MD, P.I.) (7/1/2010-9/30/2010)

Member of Expert Panel, **Protecting Privacy in Health Research.** NIH Proposal RC1 CA146501-01 (Fred H. Cate, P.I.) (2009-2012)

V. PROFESSIONAL MEMBERSHIPS AND AWARDS

Member, American College of AI in Medicine (2024 – present)

Glenn and Deborah Renwick Faculty Fellow in AI and Ethics, Herbert Wertheim College of Engineering, University of Florida (October 2023 – present)

Affiliate Member, American College of Medical Genetics and Genomics (2021 – 2024)

American Law Institute (2016 – present) (elected to membership January 2016)

Member, State Bar of Texas (2000 – present) (licensed and in good standing)

Member, State Bar of New York (1996 – present) (licensed and in good standing)

Affiliate, State Bar of Florida (2020 – present) (non-practicing affiliate status in Florida)

Senior Member and Life Member, Institute of Electrical and Electronics Engineers (2006-present); Corresponding Member, IEEE Medical Technology Policy Committee (2006-2008); IEEE member (since engineering school)

Tau Beta Pi engineering honor society (life member)

Order of the Barons Professor of the Year Award (2016-2017)

VI. UNIVERSITY, PROFESSIONAL, AND FEDERAL ADVISORY COMMITTEE SERVICE ACTIVITIES

A. Service to the Levin College of Law (2020 – present)

Member, Curriculum Committee (September 2025 – present)
Member, Non Tenure Track Appointments Committee (September 2024 – December 2024)
Member, Academic Success and Bar Passage Committee (May 2023 – May 2024)
Member, Promotion & Tenure Committee (May 2022 – May 2024)
Member, Faculty Development Committee (May 2021 – May 2022)
Member, Ad Hoc FinTech Reading Group (May 2021 – August 2021)
Member, Curriculum Committee (September 2020 – May 2021)

B. Service to the University of Florida (2020 – present)

Director, AI Alignment, Intelligent Critical Care Center (IC3), University of Florida College of Medicine (9/2024 – present)

Member, AI Governance and Policy Drafting Committee, UFHealth (11/2024 – present)

Member, University of Florida College of Medicine, Working Group on AI, Software as a Medical Device, and Quality Improvement (chaired by Dr. Patrick Tighe) (3/2024 – present)

Member, University of Florida College of Pharmacy, Regulatory Science Working Group (convened by Dean Peter Swaan) (9/2023 – present)

Member, Planning Committee, University of Florida College of Medicine AI4Health Conference (held April 2024, Orlando, Florida)

Member, University of Florida Health Science Center AI Steering Committee (Appointments Committee) (9/2021 – 12/2023)

C. Professional and Federal Advisory Committee Service

Member, American College of Medical Genetics and Genomics, Working Group on The 21st Century Cures Act Information Blocking Provisions (8/2023 – 5/2024)

Peer Reviewer, New England Journal of Medicine – AI (11/2023 – present)

Co-chair, Ethical and Trustworthy AI Working Group, NIH Bridge2AI Program (4/2023-4/2024)

Member, Planning and Drafting Committee, Symposium for Responsible AI for Social and Ethical Healthcare (RAISE): An International Meeting (held October 30-31, 2023, Cape Neddick, Maine)

Participant, American Privacy Law Project (held September 21, 2023, The University of Arizona DC Center, Washington, DC)

Advisory Board Member, NIH/NHGRI-funded Center for ELSI Resources and Analysis (CERA) ("ELSI hub") (co-led by the Stanford Center for Biomedical Ethics and the Division of Ethics at Columbia University in partnership with The Hastings Center and the Personal Genetics Education Project at Harvard University) (5/2022 – 4/2024)

Member, National Academies of Sciences, Engineering, and Medicine Standing Committee on Aerospace Medicine and the Medicine of Extreme Environments (12/2018-12/2022, reappointed 12/2022 – 12/2024)

Member, American College of Medical Genetics and Genomics Working Group on the HIPAA

Designated Record Set (12/2021-10/2023)

Participant, multidisciplinary Expert Advisory Panel convened by the U.S. Government Accountability Office (GAO) and the National Academies of Science, Engineering, and Medicine to advise on report entitled, "Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning Technologies for Medical Diagnostics" (9/2022) *available at:* https://www.gao.gov/products/gao-22-104629

Peer reviewer, Journal of Law & the Biosciences (2022-2023), Stanford Law Review (3/2023), Columbia Law Review Forum (2/2023)

Participant and Lead for multidisciplinary Expert Advisory Panel convened by the U.S. Government Accountability Office (GAO) and the National Academies of Science, Engineering, and Medicine to advise on report entitled, "Artificial Intelligence in Health Care: Benefits and Challenges of Technologies to Augment Patient Care" (11/2020) *available at:* https://www.gao.gov/products/GAO-21-7SP

Participant and Lead for multidisciplinary Expert Advisory Panel convened by the U.S. Government Accountability Office (GAO) and the National Academies of Science, Engineering, and Medicine to advise on report entitled, "Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning in Drug Development" (1/2020) *available at:* https://www.gao.gov/products/GAO-20-215SP

Appointee, National Committee on Vital and Health Statistics (2015-2017) and Co-chair, Privacy Subcommittee and De-Identification Working Group (2016-2017); participant in "Beyond HIPAA" expert working group (2019)

Member, Privacy Panel, U.S. Food & Drug Administration Mini-Sentinel and Sentinel System Projects (2010-2019)

Member, National Heart, Lung, and Blood Advisory Council (NHLBAC) Working Group on Emerging Issues in Data Sharing (EIDS) (10/2018)

Member, U.S. National Academies of Science, Engineering, and Medicine Committee on Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System (2016-2017)

Member, Planning Board for the U.S. Food & Drug Administration's Center for Devices and Radiological Health's National Evaluation System for Health Technology (NEST) (2016-2017)

Plenary session moderator; co-lead, breakout session, Return of Results Workshop, Jackson Heart Study Coordinating Center, University of Mississippi Medical Center (Aldolfo Correa, MD, MPH, PhD, PI) (April 4, 2017)

Member, GP-Write Consortium (2016-2017), a multidisciplinary group of about 200 scientists and scholars in 14 nations for preparation of white paper on genome synthesis for

testing in cell lines; co-lead, with bioethicist Jonathan Moreno, of the Ethics and Legal Studies Group for /GP-Write (2017); Participant and Panelist, Human Genome Project, Part II (HGP/Write) Kick-Off Meeting, Harvard Medical School (May 10, 2016)

Peer Reviewer, National Academies of Science, Engineering, and Medicine, Making the Living World Engineerable: Science, Practice, and Policy Proceedings of a Workshop (2016)

Member, Institute of Medicine Committee on Accessible and Affordable Hearing Health Care for Adults (2015-2016)

Participant, White House/Stanford Medicine X Design Workshop on Engaging Participants as Partners in Research (June 2, 2016); White House Precision Medicine Initiative Summit (February 25, 2016) and White House Champions of Change in Precision Medicine meeting (July 8, 2015)

Member, U.S. Food and Drug Administration's Sentinel System Patient Engagement Working Group (2015-2016)

Guest Scholar, U.S. Food & Drug Administration, Center for Devices and Radiological Health (August 2016)

Member, Food and Drug Law Institute, Academic Programs Committee (2013-2016)

Participant, International Summit on Human Gene Editing, sponsored by the U.S. National Academy of Science, U.S. National Academy of Medicine, The Chinese Academy of Sciences, and The Royal Society (December 1-3, 2015)

Visiting Scholar, Center for Law, Ethics, and Applied Research (CLEAR) in Health Information, Indiana University (August 2015)
Distinguished Health Scholar, Seton Hall Law School (March 2015)

Faculty mentor, American Society of Law, Medicine, and Ethics (ASLME) Health Law Scholars Program (2015)

Member, Institute of Medicine Committee on Ethics Principles and Guidelines for Health Standards for Long Duration and Exploration Spaceflights (2013-2014)

Member, Texas Medical Center Clinical Research Design Team (2014)

Member, Steering Committee, UH Faculty Senate 15th Annual Scholarship and Community Conference, *Greater Houston's Health: Urban Healthcare in the 21st Century* (2013)

Program Co-chair, Greenwall Foundation Annual Meeting (May 1-2, 2013)

Adjunct Professor of Clinical Pharmacology, Indiana University School of Medicine (2007 – 2015) and Affiliated Investigator, IU Center for Bioethics (2009-2015)

Member, External Advisory Committee, Duke University Clinical and Translational Sciences Institute under NIH Clinical and Translational Sciences Award (Robert Califf, M.D., P.I.) (2008- 2012)

Peer reviewer for U.S. Agency for Healthcare Quality and Research publication entitled REGISTRIES FOR EVALUATING PATIENT OUTCOMES: A USER'S GUIDE (2013); peer reviewer, GENETICS IN MEDICINE (2013, 2016), NEW ENGLAND JOURNAL OF MEDICINE (2013), CHEST (2013); JOURNAL OF GENERAL INTERNAL MEDICINE (2013), PHARMACOEPIDEMIOLOGY & DRUG SAFETY (2011); peer reviewer for genetics-related grant proposals submitted to The Wellcome Trust Biomedical Ethics Research Fellowship Program, United Kingdom (2011-2012)

Member, Program Committee, *Third International Health Privacy Summit* (Georgetown Law Center, 6/2013) and *First International Health Privacy Summit* (Georgetown Law Center, 6/2011)

Peer reviewer for Institute of Medicine consensus report entitled ETHICAL AND SCIENTIFIC ISSUES IN STUDYING THE SAFETY OF APPROVED DRUGS (Ruth R. Faden & Steven N. Goodman, Co-chairs) (2012)

Member, Institute of Medicine Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process (2010-2011)

Member, Program Committee for March 8, 2010 *FDA Sentinel Initiative Meeting Series: Legal Issues in Active Medical Product Surveillance*, convened by the Engelberg Center for Health Care Reform at the Brookings Institution under sponsorship of FDA

Member, Oversight Task Force of U.S. Department of Health & Human Services Secretary's Advisory Committee on Genetics, Health, & Society (2007-2008)
Health Law Scholar, ASLME/Saint Louis University Health Law Scholars Workshop (2007)

Member, American Bar Association Special Committee on Bioethics and the Law (2006-2011); Liaison of ABA Administrative Law Section to the Special Committee on Bioethics (2005-2006)

Member, Legal Working Group, Health Information Security and Privacy Collaboration (HISPC) for Indiana (2006)

VII. PUBLICATIONS

Works in Progress/Forthcoming Works

Barbara J. Evans, Eric S. Rosenthal &Azra Bihorac, *Reconceiving Safety Regulation for AI/ML Medical Software***,** VANDERBILT JOURNAL OF ENTERTAINMENT AND TECHNOLOGY LAW (Symposium Issue, "Evolving Healthcare Technologies: Legal Challenges in AI, Regulation, and Data Privacy," forthcoming 2026)

Barbara J. Evans, Impacts of the U.S. Department of Justice Data Security Program on Genomic Data Sharing, American Journal of Bioethics, *forthcoming* 2025 (invited peer commentary on article entitled "The Genetic Data Market" by Kayte Spector-Bagdady)

Barbara J. Evans, *The Law of Open Medical Data: Past Application and Future Challenges* (type: law review, to be submitted Fall 2025)

Barbara J. Evans, Eric S. Rosenthal & Azra Bihorac, *Integrating Human and Artificial Intelligence in Clinical Care: Lessons from the Maya* (type: medical article, submitted and under peer review)

Ellen W. Clayton, Barbara J. Evans, et al., *Biomedical Data Repositories Require Governance for AI/ML Applications at Every Step,* JOURNAL OF THE AMERICAN MEDICAL INFORMATICS ASSOCIATION (type: medical article, under revision in response to peer review comments).

Published Works

Written works are sorted into three categories: (1) legal writing, (2) peer-reviewed scientific and medical journal articles, (3) other writing such as advisory committee reports and comments filed in regulatory proceedings.

A. Legal Writing

Barbara J. Evans, *Ethical Oversight and Social Licensing of Portable MRI Research*, 52 JOURNAL OF LAW, MEDICINE, AND ETHICS 851-867 (2024, *published* January 2025) (Supplement entitled, "Highly Portable and Cloud-Enabled Neuroimaging Research: Confronting Ethics Challenges in Field Research with New Populations," reporting results of National Institutes of Mental Health RF1MH123698) (peer-reviewed law journal)

Francis X. Shen, Susan M. Wolf, Frances Lawrenz, Donnella S. Comeau, **Barbara J. Evans**, Damien Fair, Martha J. Farah, Michael Garwood, S. Duke Han, Judy Illes, Jonathan D. Jackson, Eran Klein, Matthew S. Rosen, Efrain Torres, Paul Tuite, J. Thomas Vaughan, *Conducting Research with Highly Portable MRI in Community Settings: A Starter Guide to Navigating Ethical Issues and ELSI Checklist*, 52 JOURNAL OF LAW, MEDICINE, AND ETHICS 769-785 (2024, *published* January 2025) (Supplement entitled, "Highly Portable and Cloud-Enabled Neuroimaging Research: Confronting Ethics Challenges in Field Research with New Populations," reporting results of National Institutes of Mental Health RF1MH123698) (peer-reviewed law journal)

Barbara J. Evans, *Private Ordering is Ubiquitous in Health Care, but Why?* 20-31 *in* Health Law as Private Law: Pathology or Pathway? (I. Glenn Cohen, Christopher T. Robertson, Wendy Epstein, and Susannah Baruch *eds*., Cambridge University Press, 2025) (competitively selected academic conference proceedings)

Barbara J. Evans, *FDA Regulation of Physicians' Professional Speech*, 5 JOURNAL OF FREE SPEECH LAW 1-65 (2024), https://www.journaloffreespeechlaw.org/ (peer-reviewed law journal)

Francis X. Shen, Susan M. Wolf, Frances Lawrenz, Donnella Comeau, Kafui Dzirasa, **Barbara J. Evans**, Damien Fair, Martha J. Farah, S. Duke Han, Judy Illes, Jonathan Jackson, Eran Klein, Karen S. Rommelfanger, Matthew S. Rosen, Efraín Torres, Paul Tuite, J. Thomas Vaughan & Michael Garwood, *Ethical, Legal, and Policy Challenges in Field-based Neuroimaging Research Using Emerging Portable MRI Technologies: Guidance for Investigators and for Oversight,* 10 JOURNAL OF LAW & THE BIOSCIENCES 1-65 (2024) (peer-reviewed law journal)

Barbara J. Evans, *The HIPAA Privacy Rule at Age 25: Privacy for Equitable AI,* 50 FSU LAW REVIEW 741-810 (2023) available at: https://www.fsulawreview.com/article/the-hipaa-privacy-rule-at-age-25-privacy-for-equitable-ai/ (general law review)

Barbara J. Evans, *In the Medical Privacy of One's Own Home: Four Faces of Privacy in Digital Home Health Care* 15-26, *in* Digital Health Care Outside of Traditional Clinical Settings: Ethical, Legal and Regulatory Challenges and Opportunities (I. Glenn Cohen, Daniel B. Kramer, Julia Adler-Milstein, and Carmel Shachar *eds.*, Cambridge University Press, May 2024) (competitively selected academic conference proceedings)

Barbara J. Evans, *Rules for Robots, and Why Medical AI Breaks Them*, 10 JOURNAL OF LAW & THE BIOSCIENCES 1-35 (2023), https://academic.oup.com/jlb/article/10/1/lsad001/7042583 (peer-reviewed law journal)

Marwan K. Tayeh, Margaret Chen, Stephanie M. Fullerton, Patrick R. Gonzales, Samuel J. Huang, Lauren J. Massingham, Julianne M. O'Daniel, Douglas R. Stewart, Ashlee R. Stiles & **Barbara J. Evans**, on behalf of the Laboratory Quality Assurance Committee and the Social, Ethical and Legal Issues Committee of the American College of Medical Genetics and Genomics, *The HIPAA Designated Record Set for Clinical Genetics and Genomics Testing: A Points to Consider Statement of the American College of Medical Genetics and Genomics*, 25 GENETICS IN MEDICINE 1-14 (*published in print* March 2023, *online ahead of print* December 2022), doi: 10.1016/j.gim.2022.11.010 (peer-reviewed journal)

Julia Adler-Milstein, Nakul Aggarwal, Mahnoor Ahmed, Jessica Castner, **Barbara Evans**, Andrew A. Gonzalez, Cornelius A. James, Steven Lin, Kenneth D. Mandl, Michael E. Matheny, Mark P. Sendak, Carmel Shachar, Asia Williams, *Meeting the Moment: Reducing Barriers and Facilitating Clinical Adoption of AI in Medical Diagnosis* (National Academy of Medicine Discussion Paper, September 2022) *at* https://nam.edu/wp-content/uploads/2022/09/Meeting-the-Moment-Addressing-Barriers-and-Facilitating-Clinical-Adoption.pdf (peer-reviewed National Academies discussion paper)

Robbert Zusterzeel, Benjamin A. Goldstein, **Barbara J. Evans**, Thomas Roades, Kerra Mercon & Christina Silcox, *Evaluating AI-Enabled Clinical Decision Clinical Decision and Diagnostic Support Tools Using Real-World Data* (Duke-Margolis Center for Health Policy White Paper, 2022) at https://healthpolicy.duke.edu/publications/evaluating-ai-enabled-clinical-decision-and-diagnostic-support-tools-using-real-world (peer-reviewed white paper)

Barbara J. Evans & Frank Pasquale, *Product Liability Suits for FDA-Regulated AI/ML Software, in* Innovation and Protection: The Future of Medical Device Regulation 22-35 (I. Glenn Cohen, Timo Minssen, W. Nicholson Price II, Christopher Robertson & Carmel Shachar *eds.,* Cambridge University Press, 2022), at https://www.cambridge.org/core/books/future-of-medical-device-regulation/product-liability-suits-for-fdaregulated-aiml-software/4763827FFF6058FA1886CD60722B5339 (competitively selected academic conference proceedings)

Barbara J. Evans, *Programming Our Genomes, Programming Ourselves: The Moral and Regulatory Limits of Self-Harm in Do-It-Yourself Gene Editing*, in Consumer Genetic Technologies: Ethical and Legal Considerations 129-144 (I. Glenn Cohen, Nita A. Farahany, Henry T. Greely & Carmel Shachar, *eds.,* Cambridge University Press, 2021) (competitively selected academic conference proceedings)

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Barbara J. Evans, Mark A. Rothstein, Ellen W. Clayton, Susan M. Wolf, *Comments of Four Privacy Law Scholars in Docket No. HHS-OCR-0945-AA00: Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers To, Coordinated Care and Individual Engagement, Federal Register, Vol. 86, No. 12, 6446-6538*, (*filed on May 5, 2021 at* www.regulations.gov, tracking no. koc-2g4s-bzo3) (public comments in regulatory proceeding)

Barbara J. Evans, *Reinventing Biotechnology Regulations*, THE ENVIRONMENTAL FORUM 40 (Environmental Law Institute, March/April 2021), *available at* https://www.eli.org/sites/default/files/docs/tef/tef-mar-apr-2021-rejeski-maxon.pdf (solicited commentary)

Member, Expert Advisory Panel for report entitled, ARTIFICIAL INTELLIGENCE IN HEALTH CARE: BENEFITS AND CHALLENGES OF TECHNOLOGIES TO AUGMENT PATIENT CARE (U.S. Government Accountability Office and the National Academies of Science, Engineering, and Medicine, November 2020), *available at:* https://www.gao.gov/products/GAO-21-7SP (co-authored federal advisory committee technical report)

Barbara J. Evans & Ellen W. Clayton, *Federal COVID-19 Response Unlawfully Blocks State Public Health Efforts*, BILL OF HEALTH: EXAMINING THE INTERSECTION OF HEALTH LAW, BIOTECHNOLOGY, AND BIOETHICS (October 22, 2020) (blog post)

Member, Expert Advisory Panel for report entitled, ARTIFICIAL INTELLIGENCE IN HEALTH CARE: BENEFITS AND CHALLENGES OF MACHINE LEARNING IN DRUG DEVELOPMENT (U.S. Government Accountability Office (GAO) and the National Academies of Science, Engineering, and Medicine, January 2020), *available at:* https://www.gao.gov/products/GAO-20-215SP (co-authored federal advisory committee technical report)

Barbara Evans, Comment Letter on Clinical Decision Support Software Draft Guidance for Industry and Food and Drug Administration Staff (Jan. 2, 2020), at https://www.regulations.gov/comment/FDA-2017-D-6569-0104 (public comments in regulatory proceeding)

Kristen Rosati, Naomi Jorgenson & Barbara Evans, Sentinel Initiative Principles and Policies: HIPAA and Common Rule Compliance in the Sentinel Initiative (FDA Sentinel System Operations Center, 2018)

Barbara J. Evans, *A Tale of Two Condos: HCAD's Black-box Property Valuations Hurt Homeowners*, HOUSTON CHRONICLE A17 (July 18, 2018) (Op-ed)

Member of Committee for preparation of report, NATIONAL ACADEMIES OF SCIENCE, ENGINEERING, MEDICINE FUTURE BIOTECHNOLOGY PRODUCTS AND OPPORTUNITIES TO ENHANCE CAPABILITIES OF THE BIOTECHNOLOGY REGULATORY SYSTEM (2017)

Member, GP-Write Consortium and co-lead, Ethical, Legal, and Social Issues working group for preparation of White Paper entitled, GENOME PROJECT-WRITE: A GRAND CHALLENGE USING SYNTHESIS, GENE EDITING AND OTHER TECHNOLOGIES TO UNDERSTAND, ENGINEER AND TEST LIVING SYSTEMS (November 30, 2016) at http://engineeringbiologycenter.org/wp-content/uploads/2016/12/GP-Write-WhitePaper.pdf

Member of National Medical Device Evaluation System Planning Board and co-author, THE NATIONAL EVALUATION SYSTEM FOR HEALTH TECHNOLOGY (NEST): PRIORITIES FOR EFFECTIVE EARLY IMPLEMENTATION (Duke University, Duke – Robert J. Margolis Center for Health Policy, 2016)

Member of National Medical Device Evaluation System Planning Board and co-author, BETTER EVIDENCE ON MEDICAL DEVICES: A COORDINATING CENTER FOR A 21ST CENTURY NATIONAL MEDICAL DEVICE EVALUATION SYSTEM (Duke University, Duke – Robert J. Margolis Center for Health Policy, 2016)

Member of Committee for preparation of report: INSTITUTE OF MEDICINE, COMMITTEE ON ACCESSIBLE AND AFFORDABLE HEARING HEALTH CARE FOR ADULTS, HEARING HEALTH CARE: PRIORITIES FOR IMPROVING ACCESS AND AFFORDABILITY (National Academies Press, 2016), available at https://www.nap.edu/catalog/23446/hearing-health-care-for-adults-priorities-for-improving-access-and

Co-author, Comments dated January 6, 2016 by Individual Members of the National Academy of Medicine Leadership Consortium for Value and Science-Driven Health Care's Clinical Effectiveness Research Innovation Collaborative (CERIC) on U.S. Department of Health and Human Services (HHS) Proposed Rule: Federal Policy for the Protection of Human Subjects (Docket HHS-OPHS-2015-0008), *available at* http://www.regulations.gov/comment/HHS-OPHS-2015-0008-1427

Comments dated January 5, 2016 by Barbara J. Evans on U.S. Department of Health and Human Services (HHS) Proposed Rule: Federal Policy for the Protection of Human Subjects (Docket HHS-OPHS-2015-0008), available at https://www.regulations.gov/comment/HHS-OPHS-2015-0008-1424

Platt, R., C. Dezii, B. Evans, J. Finkelstein, D. Goldmann, S. Huang, G. Meyer, H. Pierce, V. Roger, L. Savitz, and H. Selker. 2015. *Revisiting the Common Rule and continuous improvement in health care: A learning health system perspective.* National Academy of Medicine, Washington, DC, at http://nam.edu/perspectives-2015-revisiting-the-common-rule-and-continuous-improvement-in-health-care-a-learning-health-system-perspective/

Barbara J. Evans & Gail P. Jarvik, joined by 17 genomics researchers, Public Comments filed in Dockets FDA-2011-D-0360: Framework for Regulatory Oversight of Laboratory Developed Tests; Draft Guidance, 79 Fed. Reg. 59,776 (October 3, 2014) and FDA-2011-D-0357: FDA Notification and Medical Device Reporting for Laboratory Developed Tests; Draft Guidance, 79 Fed. Reg. 59,779 (October 3, 2014*), filed February 2, 2015, available at* http://www.regulations.gov/comment/FDA-2011-D-0360-0171

Member of Committee for preparation of report: INSTITUTE OF MEDICINE, COMMITTEE ON ETHICS PRINCIPLES AND GUIDELINES FOR HEALTH STANDARDS FOR LONG DURATION AND EXPLORATION SPACEFLIGHTS: HEALTH STANDARDS FOR LONG DURATION AND EXPLORATION SPACEFLIGHTS: ETHICS PRINCIPLES, RESPONSIBILITIES, AND DECISION FRAMEWORK (2014) at http://www.nap.edu/catalog.php?record_id=18576

Co-author and Workgroup Leader for report: DEVELOPING APPROACHES TO CONDUCTING RANDOMIZED TRIALS USING THE MINI-SENTINEL DISTRIBUTED DATABASE (Mini-Sentinel Operations Center and Clinical Trials Transformation Initiative, 2014)

Member of Committee for preparation of report: INSTITUTE OF MEDICINE, COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS (2011), available from the National Academies Press, http://www.nap.edu/catalog.php?record_id=13150

Barbara J. Evans, Human Subjects Research Protection: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators (Docket No. HHS OPHS-2011-0005, October 25, 2011), https://www.regulations.gov/comment/HHS-OPHS-2011-0005-0822 (commenting on proposed amendments to 45 C.F.R. pt. 46 and 21 C.F.R. pts. 50, 56)

Kristen Rosati, Barbara Evans & Deven McGraw, HIPAA and Common Rule Compliance in the Mini-Sentinel Pilot (Mini-Sentinel Operations Center, 2010 & 2013)

Barbara J. Evans, RIN 0991-AB57: Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act (Docket No. HHS-OCR-2010-0016, Sept. 10, 2010) https://www.regulations.gov/comment/HHS-OCR-2010-0016-0086 (commenting on constitutional constraints affecting implementation of the cost-based fee for preparation and transmittal of data under section 13405(d) of the HITECH Act)

Member of Committee for preparation of report: INSTITUTE OF MEDICINE, COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, MEASURING BPOSTMARKET PERFORMANCE AND OTHER SELECT TOPICS (Theresa Wizemann, ed., 2010)

Member of Committee for preparation of workshop report: INSTITUTE OF MEDICINE, COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, BALANCING PATIENT SAFETY AND INNOVATION (Theresa Wizemann, ed., 2010)

Barbara J. Evans, Issue Brief: Appropriate Human-Subject Protections for Research Use of Sentinel System Data, in FDA SENTINEL INITIATIVE MEETING SERIES: LEGAL ISSUES IN ACTIVE MEDICAL PRODUCT SURVEILLANCE (Engelberg Center for Health Care Reform at the Brookings Institution, 2010)

Member of Oversight Task Force and contributing author, U.S. SYSTEM OF OVERSIGHT OF GENETIC TESTING: A RESPONSE TO THE CHARGE OF THE SECRETARY OF HEALTH AND HUMAN SERVICES, REPORT OF THE SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY (April 2008)

Evans, Barbara J., Investing in Russian Power, in Power in Eastern Europe, a Special Report of THE FINANCIAL TIMES, Issue 59, 16-18 (11 June 2001)

Theses and Dissertation

Thesis for the Degree of LL.M. in Health Law, The University of Houston Law Center (2003) (revised and published under the title Inconsistent Regulatory Protection Under the U.S. Common Rule, cited above)

Mine Capacity Utilization During Recessionary Periods: Operating Strategy for the U.S. Copper Industry. Dissertation for the Degree of Doctor of Philosophy in Earth Sciences with specialization in Mineral Economics, Stanford University (1984)

Statistical Techniques for Subsurface Reservoir Management. Thesis for the Degree of Master of Science in Applied Earth Science with specialization in Applied Hydrogeology, Stanford University (1982)

Legal Writing Award

Second Prize, Sixth Annual Student Health Law Writing Competition (2004) sponsored by Epstein, Becker & Green P.C., for LL.M. student paper, The Six Enigmas of Bioethical Jurisprudence: Why Bioethics Fails to Produce Constitutional Rights

VIII. PRESENTATIONS

Scheduled Fall 2025 appearances

Speaker and Panelist, National Academies of Science, Engineering, and Medicine Forum on Regenerative Medicine: Workshop on AI (Washington, D.C., November 18, 2025, via Webinar)

Speaker and Panelist (with Dr. Kenneth Oye), *Next Steps in Network Ethics*, NetEthics: Developing Tools for Research Networks to Support Ethical & Responsible Research Conference (November 14, 2025, via Webinar)

Keynote speaker, Renwick Summit for AI Ethics (San Francisco, November 13-14, 2025)

Prior appearances

Keynote Speaker, *Ethical Considerations for AI in Clinical Care*, American College of AI in Medicine Annual Conference (Chicago, Illinois, September 20, 2025)

Speaker and Panelist (with Vivian S. Lee, Gilbert S. Omenn & Kathleen Sullivan), *Should regulatory agencies define normative frameworks for AI clinical behavior?* RAISE 2.0: Responsible AI for Social and Ethical Healthcare) (Portland, Maine, September 19, 2025)

Module 2: Regulatory Landscape of Biomedical AI: Data Privacy Regulations (Gainesville, Florida, August 21, 2025) (studio-produced video recording for inclusion in College of Medicine's "AI Passport for Biomedical Research" Digital Experiential Learning Community for Upskilling in Artificial Intelligence online training program)

The Clinical Care Data Governance Challenge, Session 1: Data Governance and Downstream Usage, NIH Bridge2AI Open House (Bethesda, Maryland, May 22, 2025)

Panelist (with Tom Pollard, Pablo Gazmuri, Matt Howard, Satra Ghosh, Lucila Ohno-Machado), *Data Sustainability Panel*, NIH Bridge2AI All Hands Meeting (Bethesda, Maryland, May 20, 2025)

Achieving Sustainable Operation of the Bridge2AI Strategic Biomedical Data Asset, NIH Bridge2AI All Hands Meeting (Bethesda, Maryland, May 20, 2025)

Speaker, *Clinical Care Data Ethics Update*, and Panelist (with Vardit Ravitsky, Bradley Malin, and Nick Evans), *Ethics Pillar Consortium Progress*, NIH Bridge2AI All Hands Meeting (Bethesda, Maryland, May 20, 2025)

Sustainable Access to Data for Biomedical AI: Guidance for Industry, Advisory Board Meeting, Glenn & Deborah Renwick Faculty Fellows in AI Ethics Program, University of Florida Herbert Wertheim College of Engineering (Gainesville, Florida, May 16, 2025)

Briefing - Department of Justice Data Security Program (28 C.F.R. Part 202 and three guidances issued 4/11/2025), NIH Bridge2AI Data Sharing and Dissemination Committee, University of South Florida College of Medicine (Webinar, May 14, 2025)

Moderator (for Leo Anthony Celi and Thinh Nguyen), *AI Policy Forum: The Promise and Peril of Open Data* (University of Florida Intelligent Clinical Care Center, April 3, 2025)

Guest Lecturer, *Rules for Robots, and Why Medical AI Breaks Them: A New Ethical, Legal, and Social Implications Framework for the Age of Medical AI*, Duke University Clinical Research Training Program (Webinar, March 24, 2025)

Speaker and Panelist (with J. Mark Ansermino (moderator) and Leo Anthony Celi, Agnes Kiragga, and Rishikesan Kameleswaran), *Equity and Safety for AI in Global Health*, Consortium of Universities for Global Health 2025 Conference entitled, "Innovating and Implementing in Global Health for a Sustainable Future" (Atlanta, Georgia, February 22, 2025)

Speaker, *Software Developers and the Corporate Practice of Medicine Doctrine*, Vanderbilt Journal of Entertainment and Technology Law Symposium (Nashville, February 7, 2025)

Speaker, *Corporate Practice of Medicine and Oversight of AI/ML Clinical Decision Support Tools*, International Center for Law and Economics Corporate Practice of Medicine Roundtable (webinar, January 9, 2025)

Speaker, *Is it Time to Retire the Concept of De-identification? No, But it is Time to Start Enforcing It,* and panelist (with Luke Gelinas, Jonathan Green, and Kayte Spector-Bagdady) in Multi-Regional Clinical Trials Center of Brigham & Women's Hospital and Harvard, Bioethics Collaborative webinar entitled, "Is it Time to Retire the Concept of De-identification?" (Webinar, December 12, 2024)

Speaker, *Radicalizing ELSI: A New Ethical, Legal, and Social Implications Framework for the Age of Medical AI,* McWilliams School of Biomedical Informatics at the University of Texas Health Science Center – Houston (Houston, Texas December 11, 2024)

Speaker, *Building Ethical Pylons for the Bridge2AI*, and panelist, Ethical and Trustworthy AI Discussion, NIH Bridge2AI Face-to-Face Meeting (La Jolla, California, December 6, 2024)

Symposium paper presentation (with co-authors Azra Bihorac and Eric Rosenthal, with Chiafeng Lu and Eric Solowey as commenters), *The Challenges of Regulating Information as Medicine*, Food & Drug Law Institute 2024 Symposium entitled, "From Past to Progress: Envisioning the Future of FDA Law and Regulation" (Webinar: November 13, 2024)

Speaker, *Coordinated Framework for Regulation of Biotechnology* and *Loper-Bright in an Empirical Perspective*, and Panelist (with Sarah Carter, Keith Matthews, Chris Wozniak, Richard Murray, and Mary Maxon), CalTech Linde Center for Science, Society, and Policy (LCSSP) Seminar Series (Webinar, October 16, 2024).

Speaker, *Legal Challenges for Biomedical Digital Twins,* Interagency Modeling & Analysis Group conference, "Setting up Teams for Biomedical Digital Twins," Part 2 - Addressing Gaps &

Challenges for Successful BDT Implementation (Bethesda, Maryland, October 1, 2024) (remote participation)

Speaker, *Ethical and Privacy Concerns with Biomedical Digital Twins*, Interagency Modeling & Analysis Group conference, "Setting up Teams for Biomedical Digital Twins," Session 1 – Addressing Gaps and Challenges for Successful BDT Implementation (Bethesda, Maryland, September 30, 2024) (remote participation)

Panelist, *Ethical, Security Issues, Team Science, and Governance*, Interagency Modeling and Analysis Group, "Setting up Teams for Biomedical Digital Twins," Breakout Session 1 – Generating Requirements for BDT (Bethesda, Maryland, September 30, 2024) (remote participation)

Keynote Address, *Patients' Rights in the Time of AI, Session 6: Regulatory and Normative Aspects of AI in Clinical Decision Support,* International Conference on Complex Acute Illness Annual Conference (ICCAI 2024) co-hosted by the Uniformed Services University, Maximizing Clinical Impact of Algorithmic Innovation (AI) in Critical Illness From Academia and Industry to Government (Bethesda, Maryland, September 6, 2024)

Keynote Address, *Trusting AI-driven Tools in the Learning Healthcare System*, One Florida Clinical Research Network and U.F. Clinical & Translational Science Institute Annual Conference, Transforming Patients-Centered Health Care Delivery Through AI-enabled Learning Health Systems (Amelia Island, Florida, September 4, 2024)

Speaker, *Cross-disciplinary Perspectives on Military Uses of AI* and Moderator, *Human Machine Integration (HMI) and Artificial Intelligence, Block #1, a Moderated Discussion of Philosophy and Science Perspectives with Dr. Amar Marathe and Dr. Kevin Schieman,* Second Annual Future of Warfare and the Law Symposium (United States Army Futures Command in partnership with the Lieber Institute at West Point and the University of Texas at Austin Robert Strauss Center for International Security and the Law, Austin, Texas May 13-14, 2024)

Panelist (with Vardit Ravitsky (moderator) and Joseph Yracheta, Anita Ho, and Oita Coleman), on *Trust in the Context of Rapidly Evolving Technology*, Bridge2AI Voice AI Symposium (Tampa, Florida, May 2, 2024)

Panelist, *Large Language Models – Algorithmic Bias* (with Dr. My Thai, UF Wertheim College of Engineering) and *Safer AI: Educating the Public vs. Heavy Regulations* (with Dr. Azra Bihorac, UF College of Medicine), Briefings for Congressional Representative Kat Cammack and Jessica Norfleet (Malachowsky Hall, April 24, 2024)

Speaker and Panelist, *We're at an inflection point. Things must change*, and *Panelist* (with Eric S. Rosenthal, Andrew Williams, and Derek Bambauer) on *Legal Issues and Sharing and Using Data in AI.* UFHealth Second Annual AI4Health Conference: Improving Health Through Artificial Intelligence (Orlando, Florida, April 22, 2024)

Mentor, AI for Clinical Care Workshop, AI Boot Camp (Beginner Track) and Generative AI with Diffusion Models Workshop (Advanced Track) (University of Florida College of Medicine, the Herbert Wertheim College of Engineering and the Intelligent Clinical Care Center (IC), in collaboration with the Bridge2Al CHoRUS network, Lake Nona, Florida, April 21, 2024)

Speaker, *CHoRUS Ethics Pillar – Lessons Learned from Open House Readiness,* NIH Bridge2AI Face-to-Face Meeting (National Institutes of Health, Bethesda, Maryland, April 17, 2024)

Moderator, Panel II: Delving Deeper into Standards: Considering Standards of Care for a Floor and a Safe Harbor in Software Security, Legal Symposium on Software Liability (Office of the National Cyber Director, The White House, Washington, D.C. March 27, 2024)

Speaker, *First Amendment Concerns with FDA's Proposed Regulation of Laboratory-Developed Tests,* 17th Annual FlowTex Cytometry Conference (Texas Medical Center, Houston, March 27, 2024) (speech delivered via pre-recorded video because of scheduling conflict)

Panelist (with Dr. Azra Bihorac), Co-creating Consent: Digital Democracy to Protect Privacy in Medical AI (University of Florida Office of Public Policy Events, March 26, 2024)

Discussant, Listening Session on Future U.S. System for Oversight of Products Produced with Biotechnology, National Security Commission on Emerging Biotechnology, U.S. Senate (videoconference March 20, 2024)

Member and Participant, University of Florida College of Pharmacy Regulatory Science Working Group Meeting (videoconference March 14, 2024)

Member and Participant, American College of Medical Genetics and Genomics 21st Century Cures Act Working Group Meeting (videoconference March 11, 2024)

Speaker, *Who Owns the Data Used to Train AI?* Florida IP Alliance Student Branch (University of Florida Reitz Union, February 29, 2024)

Speaker and Panelist (with Derek Bambauer) *Emerging Legal Markets: IP, Technology, AI, and Health Law Webinar* (University of Florida Levin College of Law, February 28, 2024)

Speaker, *Consent and its Discontents: Access to Training Data for AI/ML Clinical Decision Support Tools* (Indiana University McKinney Law Review Virtual Symposium, February 9, 2024)

Speaker, *Data Use Agreements, Licenses, and Social License to Share Data: What can we learn from the U.K.'s Care.Data fiasco?* (Bridge2AI Data Sharing and Dissemination Committee Webinar, February 7, 2024)

Speaker, *The Data Ethics Challenge: Data Access, Control, and Privacy*, Emerging Portable Technology for Neuroimaging Research in New Field Settings (University of Minnesota Consortium on Law and Values Webinar, December 7, 2023)

Speaker, *Legal and Ethical Aspects of Regulatory Science*, Regulatory Science Summit (University of Florida College of Pharmacy, November 28, 2023)

Moderator and Co-Chair, Ethics and Trustworthy AI Discussion Group, NIH Bridge2AI Consortium Face-to-Face Meeting (UCLA, November 7, 2023)

Speaker, *A Brief History of Open Access*, Open Data and Tools Town Hall, NIH Bridge2AI Consortium Face-to-Face Meeting (UCLA, November 6, 2023)

Speaker and Panelist (with David Blumenthal, Lisa Lehmann, and Jonathan Perlin) for *Issue 3: From Dyad to Triad: To what degree is the AIM agent recognized as a distinct party to the patient-clinician relationship?,* Responsible AI for Social and Ethical Health Care (RAISE) – An International Symposium Organized by the Department of Biomedical Informatics, Harvard Medical School (Cape Neddick, Maine, October 30, 2023)

Speaker and Panelist (with David Grant and Hina Shaikh), *Algorithmic Justice*, University of Florida AI Days (University of Florida Reitz Union, Grand Ballroom, October 17, 2023)

Speaker and Panelist (with Duncan Purves and David Grant), University of Florida College of Medicine Ethics of AI Workshop for Emerging Research Scholars (University of Florida Reitz Union, Matthews Suite, October 13, 2023)

Speaker and Panelist (with Marta L. Wayne, Ann-Elisabeth Courrier, and Amber Ross), *Ethics, Data Privacy, and Governance,* Ethics and Governance of AI Through an International Lens (University of Florida Reitz Union, Chamber Room, September 6, 2023)

Speaker, *Social licensing of the use of health data in AI systems: What is the right way to decide which uses of health data in AI are permissible and on what terms?*, NIH Bridge 2AI Ethics Core Working Group Meeting (August 15, 2023) (webinar)

Speaker, *Unwanted births and Unintended Consequences: How Reproductive Rights Cases Inadvertently Shaped the Future of the AI-enabled Physician-Patient Relationship,* Petrie-Flom Annual Writer's Conference (Harvard Law School, June 23, 2023)

Speaker, *A First Amendment Critique of FDA's Guidance on Clinical Decision Support Software,* 2023 Tsai Center Summit: Food & Drug Scholars Retreat (Vail, Colorado, June 1, 2023)

Speaker, *A First Amendment Critique of FDA's Guidance on Clinical Decision Support Software*, University of Arizona Information as Medicine Workshop (videoconference, May 25, 2023)

Speaker*, Privacy and Data Security in UF AI Research* and *Panelist* (with My Thai, Duncan Purves, Jim Hoover, and David Grant), *Building Ethical AI at UF* (Reitz Union Chamber Room, University of Florida, April 28, 2023)

Participant, Software Liability Workshop (in person at Stanford University and remote via Zoom, April 25, 2023)

Speaker, *Federal Policies on Safety and Privacy of Clinical Decision Support Tools* and Panelist (with Eric S. Rosenthal, Yindalon Aphinyanaphongs, and Richard Frank), *Roundtable on AI Federal Policy and Reimbursement Considerations*, AI4Health: Improving Health Through Artificial Intelligence (Orlando, April 21, 2023)

Participant, ELSIhub/Center for ELSI Resources and Analysis Annual Programming Meeting (videoconference, April 6, 2023)

Speaker, *Sandy Sanbar Annual Lecture: Federal Policies on Safety and Privacy of Clinical Decision Support Tools,* American College of Legal Medicine, 63rd Annual Conference: Advancing Legal Medicine in an Era of Change (Orlando, February 24, 2023)

Speaker, *Informational Research Policy*, Information as Medicine Workshop, University of Arizona TechLaw (Washington, D.C., November 4, 2022)

Speaker, *Seeking a Remedy: Ethicolegal and Regulatory Aspects of Artificial Intelligence*, Crossing the Bridge to Artificial Intelligence Together: A Roadmap to Equitable AI, Neurocritical Care Society Annual Meeting (San Antonio, October 20, 2022)

Panelist, *Artificial Intelligence in Medical Diagnosis* (public webinar co-hosted by the National Academy of Medicine and U.S. Government Accountability Office, October 6, 2022) at https://nam.edu/event/artificial-intelligence-in-medical-diagnosis/

Speaker, *Sustainable AI in Clinical Care: Data Ethics for AI-enabled Clinical Health Care,* NIH/Hood College/Frederick National Laboratory Symposium: Artificial Intelligence in Cancer Research and Clinical Care: Turning Promise into Reality (September 22, 2022)

Speaker, *Four Faces of Privacy in Digital Home Health Care,* Petrie-Flom 2022 Annual Conference Writers' Workshop, Harvard Law School (June 15, 2022)

Speaker, *Computational Privacy Protections (and what they teach us about the suboptimal ways we've all been thinking about data privacy for the past 50 years)*, N.I.H. Privacy Protections for Proteomic and Metabolomic Data (P3MD) Workshop (Denver, April 22, 2022)

Speaker, *Ethical and Legal Challenges with AI/ML Medical Tools*, University of Florida Medical AI Forum (April 6, 2022)

Speaker, *Privacy for Equitable AI*, Harvard Medical School Bioethics & AI Seminary (March 24, 2022, virtual meeting)

Speaker, *Evaluating Real-World Performance of AI/ML SaMD [Software as a Medical Device]*, Public Webinar on AI/Machine Learning Regulation, Development, and Real-World Performance Evaluation, Duke-Margolis Center for Health Policy (March 22, 2022, virtual meeting)

Speaker, *Regulatory Oversight of Medical Software Under the 21st Century Cures Act,* Biomedical Engineering, Law & Policy Colloquium, Penn State University (March 21, 2022, virtual meeting)

Participant and presenter, *AI/ML Data Ecosystem Where Models Meet Data*, InnovationLab: A Data Ecosystems Approach to Ethical AI for Biomedical and Behavioral Research (NIH/KIstorm, March 14-18, 2022)

Speaker, *Diagnosing Alzheimer's with Alexa?,* Harvard Medical School/Harvard Law School Petrie Flom Center Health Policy and Bioethics Consortium (February 11, 2022, virtual meeting)

Speaker, *Reflections on Cryopreservation for Solid Organ Transplants,* ATP-Bio Ethics & Public Policy Component Working Group Meeting V (January 24, 2022, virtual meeting)

Speaker, *Special Challenges and Legal Opportunities for Governance of AI/ML Clinical Decision Support Software,* Stanford University AI + Health Conference (December 8, 2021)

Speaker, *Gender Bias and Erasure of Transgender Patients in Medical AI Tools,* M.I.T. Feminist Data Ethics Colloquium (November 22, 2021, virtual meeting)

Speaker, *FDA's Role + Privacy, Bias, and Access to HIPAA-regulated Data for AI/ML Software*, UF Health Imaging Core/Federated Learning Meeting (October 28, 2021)

Speaker, *Regulation of Foundries Computer-Aided Design of Gene Constructs*, GP-Write/Center for Excellence in Engineering Biology Annual Conference (October 22, 2021, virtual meeting)

Speaker, *CLIA Regulation and FDA's Regulation of Software in the Clinical Laboratory Bioinformatics Pipeline,* University of Maryland Direct-to-Consumer Microbiome-Based Tests Multidisciplinary Working Group Meeting (June 17, 2021, virtual meeting)

Panelist, *Ethics and Public Policy Component*, NSF Engineering Research Center for Advanced Technologies for the Preservation of Biological Systems (ATP-Bio), Working Group Meeting III (June 16, 2021, virtual meeting)

Participant, University of Florida Townhall: Bridge to AI Data Generation Projects (June 11, 2021, virtual meeting)

Participant, National Academies of Science, Engineering, and Medicine and Government Accountability Office, Expert Meeting on Machine Learning Technologies in Medical Diagnostics, Day 3 (June 8, 2021, virtual meeting)

Participant, National Academies of Science, Engineering, and Medicine and Government Accountability Office, Expert Meeting on Machine Learning Technologies in Medical Diagnostics, Day 2 (June 3, 2021, virtual meeting)

Working Group Member and participant, Ethical, Legal, and Social Issues of Portable Imaging Working Group Meeting 3 (June 2, 2021, virtual meeting)

Participant, National Academies of Science, Engineering, and Medicine/Government Accountability Office, Expert Meeting on Machine Learning Technologies in Medical Diagnostics, Day 1 (June 2, 2021, virtual meeting)

Advisory Panel Member and participant, Mirror Cells Bioethics Advisory Panel Meeting, University of California, San Diego (May 25, 2021, virtual meeting)

Member, Legal Working Group, Variant Reinterpretation – Third Annual Expert Advisory Committee Meeting, Columbia University Irving Medical Center (May 24, 2021, virtual meeting)

Member, Working Group, The Ethics of Big Data for AI in Health Research and Healthcare, NYU Langone Health and NYU Grossman School of Medicine Division of Medical Ethics (May 20, 2021, virtual meeting)

Participant, Choice of Law in Precision Medicine Research Workshop, Day 3 Georgia State University (May 7, 2021, virtual meeting)

Working Group Member and participant, Designated Record Set Working Group, American College of Medical Genetics and Genomics (May 6, 2021, virtual meeting)

Participant, Choice of Law in Precision Medicine Research Workshop, Day 2 Georgia State University (April 30, 2021, virtual meeting)

Speaker, *Conditions for sharing of protected health information (PHI) by covered entities under the HIPAA Privacy Rule*, Presentation to State Attorneys General Privacy Officers (April 29, 2021)

Participant, Choice of Law in Precision Medicine Research Workshop, Day 1 Georgia State University (April 23, 2021, virtual meeting)

Speaker, *Rules for Robots, and Why AI/ML Medical Software Breaks Them*, The Johns Hopkins University Berman Institute of Bioethics 2020-21 Seminar Series (March 22, 2021)

Speaker, Seminar for Hecht-Levi Bioethics Post-Doctoral Fellows, The Johns Hopkins University Berman Institute of Bioethics (March 22, 2021)

Speaker, *Artificial Intelligence in Health Settings Outside the Hospital and Clinic*, A Joint Web Conversation Hosted by the NAM Leadership Consortium: Collaboration for a Value & Science-Driven Health System and United States Government Accountability Office (January 21, 2021)

Speaker, *Regulation of Big Data in Health Care in the United States,* NYU Langone Health, The Hastings Center, Hasso Plattner Institut & University of Cologne Virtual Meeting on Ethical Challenges Posed by Big Data and AI in Healthcare (December 14-15, 2020).

Speaker, *Issues in FDA Regulation of Genomic Analysis and Reporting in Research and Clinical Settings,* Webinar on LawSeq[SM]: Facing the Legal Barriers to Genomic Research & Precision Medicine (University of Minnesota Consortium on Law and Values in Health, Environment & the Life Sciences, December 2, 2020)

Speaker, *Accessing Real-World Data to Evaluate Postmarket Performance of AI-enabled Clinical Decision and Diagnostic Support Software: Can the required data be accessed ethically?* (Duke-Margolis Center for Health Policy Virtual Meeting (July 22, 2020)

Speaker, *Product Liability Risks and Defenses for FDA-Regulated AI/ML Software,* Petrie-Flom Annual Conference Podcast (June 5, 2020)

Speaker, *Liability, Regulatory Compliance, and First Amendment Protections for Scientific Speech,* American College of Medical Genetics and Genomics Annual Conference Webcast entitled "The Genetics Hotline: Responsibility and Liability When Handling Unsolicited Patient Communications" (May 20, 2020)

Panelist, The Ethical, Legal, and Social Implications of Return of Results in Deep Phenotyping Research (McLean Institute for Technology in Psychiatry, Harvard Medical School, May 8, 2020).

Participant, GAO Meeting on Artificial Intelligence and Health Care Services (Washington, D.C., April 1-2, 2020)

Panelist*,* Challenges of Regulating AI in Health Care, Symposium: The Law and Policy of Artificial Intelligence in Health Care (University of Minnesota, March 27, 2020)

Panelist, Conference/Webcast on Legal Barriers to Genomic Research and Precision Medicine (Boston, March 27, 2020)

Panelist, *The Genetics Hotline: Responsibility and Liability When Handling Unsolicited Patient Communications*, American College of Medical Genetics and Genomics Annual Meeting (San Antonio, March 18, 2020)

Participant, Annual Meeting of Legal Working Group on Variant Reinterpretation (Columbia Medical School, February 24, 2020)

Speaker, *Resolving legal, regulatory, and economic barriers to clinical translation of innovative biomedical technologies*, Herbert Wertheim College of Engineering Colloquium (University of Florida, February 7, 2020)

Speaker, *Protecting the Rights of People Whose Data Are Used in Research: Is Anonymization of Genomic Information and Other Big Data a Fallacy?,* American Health Lawyers Association, Academic Medical Centers and Teaching Hospitals Institute (Washington D.C., January 30, 2020)

Regulatory Programming for Neurotechnology Researchers, Winter Meeting, NSF-funded BRAIN Industry-University Collaborative Research Consortium (Tempe, Az., December 13, 2019)

Regulatory Structures for Access to Health Data: Privacy and the Ethics of Data Use, Ethical, Legal, and Regulatory Issues address to Computational Health Informatics students (University of Houston, November 5, 2019)

Participant, University of Houston NSF I/U CRC BRAIN Center Roadmap Meeting (Houston, September 30, 2019)
Participant and Lead, Expert Meeting on AI in Drug Discovery and Development convened by , U.S. Government Accountability Office and National Academies of Science, Engineering, and Medicine (Boston, July 18-19, 2019)

Panelist, Roundtable on Balancing Privacy with Health Data Access, U.S. Department of Health & Human Services (Washington, D.C., July 15, 2019)

Co-reporter, Regulatory & Legal Working Group, National Institutes of Health, *All of Us* Research Program Ethical, Legal, and Social Issues Workshop (Rockville, Md., June 24-25, 2019)

Adequacy of Existing Regulatory Structures for Health Data: The Law and Ethics of Unconsented Data Use, Multidisciplinary Workshop on the Future of Health Data, sponsored by Media Freedom & Information Access Clinic and Information Society Project, Yale Law School and the Collaboration for Research Integrity and Transparency of Yale School of Medicine and Yale School of Public Health (June 13, 2019)

Panelist and Speaker, Results of the NIH LawSeq Project. ASLME 2019 Health Law Professor's Conference (Chicago, June 6, 2019)

Participant, University of Houston – Baylor College of Medicine Workshop on Data Analytics: Applications to Health-Related Research (Houston, May 23, 2019)

Programming the Genome, Programming Ourselves. Petrie-Flom Annual Conference on Consuming Genomics, Harvard Law School (May 17, 2019)

Balancing Stakeholder and Developer Needs: Challenges in FDA Regulation of Machine Learning Medical Software. Duke University/Greenwall Foundation Conference on AI in Healthcare (Washington, D.C., May 13, 2019)

Moderator, Panel on Genomic Data Quality. University of Minnesota Consortium on Law and Values in Health, the Environment, and the Life Sciences, National Conference/Webcast on Law, Policy, and Genomic Medicine (Minneapolis, April 25, 2019)

Individual Access as a Foundational Data Privacy Right, University of Minnesota Consortium on Law and Values in Health, the Environment, and the Life Sciences, National Conference/Webcast on Law, Policy, and Genomic Medicine (Minneapolis, April 25, 2019)

Expert Panelist, "Beyond HIPAA" Actions Working Session, National Committee for Vital and Health Statistics, Subcommittee on Privacy, Confidentiality, and Security (Silver Spring, Md., March 21, 2019)

Democratizing Medicine in a Tech-Driven World, Jaharis 2019 Symposium on Health and Intellectual Property Law, DePaul Law School (Chicago, March 14, 2019)
Expert Advisory Committee Member, Legal and Regulatory Issues in Genetic Variant Interpretation, Columbia University School of Medicine (February 15, 2019)

Individual Data Access as a Civil Right, Law and Biomedicine Colloquium, The Center for Law and Biomedical Sciences, University of Utah S.J. Quinney College of Law (February 13, 2019)

Participant, National Academies of Sciences, Engineering, and Medicine Standing Committee on Aerospace Medicine and the Medicine of Extreme Environments Meeting (Washington, D.C., December 13-14, 2018)

Panelist, The Need for New Regulation: Privacy Law, the FDA, and Beyond, Information Society Project & the Solomon Center for Health Law and Policy at Yale Law School, The Law & Policy of Robotics & Telemedicine in Health Care, New Haven (November 2, 2018)

Panelist, Data Privacy, New York Academy of Sciences, Healthcare in the Era of Big Data: Opportunities and Challenges (October 24-25, 2018)

Panelist (with Dr. Erika Petersen), Privacy Concerns in *New Paradigms for Neuromodulation with Downloadable Data*, Congress of Neurological Surgeons' Annual Meeting, Houston (October 6, 2018).

Redoubling Our Efforts to Protect Research Participants' Privacy Rights, National Heart, Lung, and Blood, Institute Workshop: Defining the NHLBI's research priorities in the ethical, legal, and social implications (ELSI) of genomics (September 12-13, 2018)

Ethical and Financial Implications of Patient Data Ownership, National Academy of Medicine Digital Learning Collaborative, Patient Ownership of Health Data: Implications for a Learning Health System (June 27-28, 2018)

The Genomic Glass House: Data Sharing, Individual Data Access, and Civil Rights, Opening Plenary Address, Curating the Clinical Genome 2018 Conference, Wellcome Genome Campus Conference Center, Cambridge University (May 23, 2018)

Participant and Speaker, Health Data, AI, and Health Informatics Workshop, Frontiers e.g., Carmel (May 2, 2018)

FDA Regulation of Mobile Health Apps, Addressing ELSI Issues in Unregulated Health Research Using Mobile Devices Project, Working Group Meeting #2, Chicago (April 24, 2018)

Participant, Land Trusts for Data Governance, Sage Assembly 2018: Algorithms and the Role of the Individual, Seattle *(*April 20, 2018)

The Ethics of Unconsented Data Use and other Big Data Bioethics Oxymorons, National Academy of Science, Engineering, and Medicine Committee for Science, Technology, and Law, 2018 Meeting, California Institute of Technology (March 15, 2018)

The Challenge of Regulating Clinical Decision Support Software After 21st Century Cures, American Journal of Law & Medicine Symposium: The 21st Century Cures Act: A Cure for the 21st Century, Boston University (January 26, 2018)

Regulating Advanced Neurotech Brain/Computer Interfaces, National Science Foundation Industry/University Collaborative Research Center, Building Reliable Advances and Innovation in Neurotechnolog (BRAIN) Project, Arizona State University (December 8, 2017)

Understanding Genomic Data Access as a Civil Right, Symposium: Refining Privacy to Improve Health Outcomes, Triangle Privacy Research Hub/Duke University/University of North Carolina, (October 25-26, 2017)

Research Data, Clinical Data, Your Data: Individual Data Access as a Civil Right, Symposium: All Data is Health Data, Indiana University McKinney School of Law (October 20, 2017)

Regulatory Alternatives for In Vivo Somatic Gene Editing Products Using CRISPR-Cas9 RNA-Protein Complexes, MedGen Seminar, University of Washington, Division of Medical Genetics (June 16, 2017)

Individual Data Access Rights, Patients as Partners in Research, Broad Institute of Harvard/MIT, the Biden Cancer Initiative, and the Emerson Collective (June 12-13, 2017)

Special Regulatory Session: Regulatory Alternatives for Human Gene Editing, American Society of Gene and Cell Therapies Annual Convention, Washington (May 11, 2017)

Opening plenary address on Ethical and Legal Frameworks for GP-Write and *closing remarks on Working Group Roadmap: Ethical, Legal, and Social Issues,* GP-Write Annual Meeting, NYU Langone Medical Center (May 9-10, 2017)

Current Regulatory Frameworks for Biotechnology Products, Congressional Research Service Disruptive Technology Series Session for Members of Congress and Congressional Staff: Advances in Gene Editing – Balancing Promise and Risk (April 28, 2017)

Regulatory Alternatives for Human Genome Surgery (presentation with Dr. Bruce Conklin), BioLawLaPalooza Conference, Stanford University (April 20, 2017)

Consumer-driven Data Commons and the Transformation of Citizen Science, Benjamin N. Cardozo School of Law Intellectual Property + Information Law Symposium (March 20, 2017)

Plenary Session 1 - HIPAA and CLIA Considerations in Return of Results to Participants, Jackson Heart Study Workshop on Return of Results from Genetic and Genomic Studies, University of Mississippi Medical Center (April 4, 2017)

Keynote address, Critical Studies of Citizen Science, Department of Global Health and Social Medicine, King's College London (March 2, 2017)

Reflections on Solidarity as a Principle in Bioethics, Book Launch Event for Biomedicine and Beyond (Barbara Prainsack & Alena Buyx), Wallace Meeting Space, Covent Garden, London (March 1, 2017)

Special Challenges of Data Sharing and Access Under the Revised Common Rule, Seton Hall University (February 24, 2017)

Special Challenges of Data Sharing and Access in the 21st Century, NIH/NHGRI e-MERGE and CSER meeting, Bethesda, Md. (February 3, 2017)

How Patients are Creating the Future of Medicine: From Citizen Science to Precision Medicine, Dienard Memorial Lecture, University of Minnesota (December 6, 2016)
Regulation of Gene Editing Technology, Symposium on Health Care and Policy, Loyola University Chicago (October 28, 2016)

Consumer-driven Data Commons, Maurer School of Law, Indiana University (October 24, 2016)

Concepts of Patient Engagement, Luncheon address for staff of FDA's Center for Devices and Radiological Health (August 17, 2016)

Update on HIPAA Individual Access Rights and Impacts of the Genetic Information Nondiscrimination Act, Interpreta, Inc. Advisory Board Meeting (August 11, 2016)

Patient/Consumer Protection in the National Evaluation System for health Technology (NEST), Seminar: Using Real World Evidence for Regulatory Decision-Making and Patient Protection in the 21st Century, FDA Center for Devices and Radiological Health (August 16, 2016)

Participant, Design Workshop on Engaging Participants as Partners in Research, co-hosted by the White House Office of Science and Technology Policy and Stanford Medicine X (June 2, 2016) (*see* http://www.law.uh.edu/news/summer2016/0606Evans.asp and the "Navigating Privacy in Biomedical Research and Open Science" resource initiated at that meeting blog.jasonbobe.net/privacy-resources/

Oxford Union Debating Society, appearing in opposition to the motion, "This House Believes the Manipulation of Human DNA is an Ethical Necessity," Oxford University (May 26, 2016), *at* https://www.youtube.com/watch?v=O4uyXpBAmXQ .

Consumer-driven Data Commons, Health Data Exploration Project Annual Meeting, University of California at San Diego (May 18, 2016)

Panelist, Ethics and Policy Considerations, HGP/Write meeting Harvard Medical School (May 10, 2016), *at* https://www.youtube.com/watch?v=9xgm4U6E-CU (starting at 19 min., 30 sec.).

Big Data and Individual Autonomy in a Crowd, Petrie-Flom Annual Conference on Big Data, Health Law, and Bioethics, Harvard Law School (May 6, 2016), *at* https://vimeo.com/166555664 (starting at 5 min., 25 sec.).

Consumer-driven Data Commons, National Medical Device Evaluation System Planning Board Meeting (May 5, 2016)

Biotechnology: Getting the Legal Framework Right, Texas Center for Superconductivity, Meeting with Distinguished Visitors from National Chung Hsing University (April 7, 2016)

Consumer-driven Genomic Information Commons, Seminar on Ethical, Legal and Social Implications of Genetics, Center for Research on Ethical/Legal/Social Implications of Psychiatric, Neurologic & Behavioral Genetics, Department of Psychiatry, Columbia University Medical Center (March 14, 2016)

Building Sustainable Information Commons for Neurotechnology Research and Regulatory Science: Charting the Legal Pathways, NSF Industry/University Collaborative Research Center Planning Meeting (Tempe, March 10-11, 2016)

Participant, Roundtable on Privacy and Data Security, White House Precision Medicine Initiative Summit (Washington, February 25, 2016) (*see* http://www.law.uh.edu/news/spring2016/0229Evans.asp)

Big Data in Genomics and Precision Medicine, BioLaw Session, Association of American Law Schools Annual Meeting (New York, January 8, 2016)

Participant and Speaker, International Summit on Human Gene Editing, sponsored by the U.S. National Academy of Sciences, National Academy of Medicine, the Royal Society, and the Chinese Academy of Sciences (Washington, DC, December 1-3, 2015), *at* https://vimeo.com/album/3704161/video/149196322)

Current Controversies in Biotech and Law, University of Houston Health Law Speakers Series (November 4, 2015)

First Amendment Issues with FDA Regulation of Genomic Testing, FDLI/Georgetown Law School Symposium: Constitutional Challenges to the Regulation of Food, Drugs, Medical Devices, Cosmetics, and Tobacco Products (October 30, 2015)

Appearance before National Academy of Sciences, Engineering, and Medicine's ad hoc study

committee on Federal Research Regulations and Reporting Requirements, in session at Rice University (October 29, 2015)

Big Data, Big Headaches: Cultivating Public Trust in an Age of Unconsented Access to Identifiable Data, University of Wisconsin Center for Predictive Computational Phenotyping Symposium: Big Data: Policy Meets Data Science (October 15, 2015)

Panelist, Genomics, University of California Santa Cruz DataLex Conference: Privacy, Big Data & The Law (October 13, 2015)

Participant, White House Champions of Change in Precision Medicine (July 8, 2014) (see http://www.law.uh.edu/news/summer2015/0715Evans.asp)

Participant, Precision Medicine Initiative Brainstorming Session, Harvard Medical School (June 25, 2015)

Reconciling Patient Access to Data with Quality Oversight, Precision Medicine Conference, Harvard Medical School (June 24, 2015)

Panelist, Engaging Patients: Building Trust and Support for Safety Surveillance Brookings Institution (June 23, 2015)

Individual Access to Health Data, Fifth International Summit on Health Information Privacy at Georgetown Law School (June 4, 2015)

Impact of Recent HIPAA-CLIA Amendments, Fifth International Summit on Health Information Privacy at Georgetown Law School (June 3, 2015)

Ownership of Data From Mobile and Wearable Health Devices, Health Data Exploration Project Meeting, U.C. San Diego *(May 13, 2015)*

2015 Distinguished Health Scholar Lecture Series, Seton Hall Law School (March 16 -19, 2015)

The Food and Drug Administration's Expanding Role in the Regulation of Genomic Research, National Aeronautics and Space Administration Genetics Meeting (February 24, 2015)

Participant, Robert Wood Johnson Foundation-funded Creative Commons Health Privacy and Data Sharing Workshop (February 18, 2015).

Recent Developments in Regulation of Genomic Testing, Baylor College of Medicine Genetics Seminar (February 2, 2015)

The Latest Legal Issues in Genomic Medicine, University of Washington Medical Genetics Colloquium (January 16, 2015)

Impact of CLIA-HIPAA Amendments and FDA Regulation on Return of Results, PRIM&R

Advancing Ethical Research Conference (December 6, 2014)

Legally Engineering: Legal Aspects of Biotechnology, University of Houston Hispanic Professional Engineers Student Organization (December 4, 2014)

Privacy, Access, and Governance Issues Affecting Large Networked Health Information Systems, University of Maryland Preeminence as an Innovator Fall Forum (October 28, 2014)

The Limits of FDA's Authority to Regulate Clinical Research Involving High-Throughput DNA Sequencing, Petrie-Flom and Food and Drug Law Institute Symposium: Emerging Issues in FDA Regulation (October 20, 2014)

FDA & Regulation of Genomic Sequencing: Implications for Return of Results, NIH Clinical Sequencing Exploratory Consortium Meeting, Bethesda, Md. (October 8, 2014)

Genomic Data Commons as a Patient Safety Imperative, Second Thematic Conference on Knowledge Commons: Governing Pooled Knowledge Resources, sponsored by the Engelberg Center on Innovation Law & Policy at New York University Law School (September 5, 2014)

Policy Issues in Next Generation Sequencing: Economic Regulation of Data Access, ASLME Health Law Professors' Conference (June 6, 2014)

Preventing Harm to Patients Who Know Too Much about Their Own Genomes, Petrie-Flom Annual Conference at Harvard Law School: Behavioral Economics, Law, and Health Policy, Harvard Law School (May 3, 2014)

Genomic Data Access after Myriad, Spring Advisory Council Dinner, Institute of Intellectual Property and Information Law (April 17, 2014)

Novel Liability Problems in Next Generation Sequencing, Roundtable on Personalized Medicine and Malpractice Liability, Arizona State University (April 4, 2014).

Participant, Workshop on Innovation in Evidence Development for Molecular Diagnostics, Scottsdale, Az. (April 3, 2014)

The Current Legal Framework of U.S. Privacy Protections, Institute of Medicine Public Workshop: Strategies for Responsible Sharing of Clinical Trial Data - Open Session (February 4, 2014)

Barriers to Genomic Communication, University of Houston Law Center Student Symposium on Recent Policy Developments in Biotechnology and Law (October 30, 2013)

Plenary speaker, First Amendment Issues with Access to Genetic Information, ASLME Health Law Professors' Conference (June 7, 2013)

Plenary speaker, Patients' Rights of Access to their Own Health Information, Third International

Summit on Health Information Privacy at Georgetown Law School (June 6, 2013)

Regulating the Return of Results Without Triggering First Amendment Problems, National Institutes of Health/Clinical Sequencing Exploratory Research Consortium (Rockville, May 23, 2013)

The Future of Prospective Medicine After FDAAA, Annual Conference of the Petrie-Flom Center at Harvard Law School (May 3, 2013)

Nonconsensual Access to Data and Biospecimens for Research and Public Health, Greenwall Foundation Annual Meeting (May 1, 2013)

EMR Use for Postmarketing Medical Product Safety Surveillance, Case Western Reserve University Law School Symposium: Balancing Privacy, Autonomy and Scientific Progress: Patients' Rights and the Use of Electronic Medical Records for Non-Treatment Purposes (April 5, 2013)

Panelist, Privacy Law Panel, Careers in Information Law, University of Houston Intellectual Property Student Organization (Feb. 27, 2013)

Investigators' First Amendment Right to Return Results to Research Participants, University of Washington Division of Medical Genetics Seminars (February 15, 2013)

Client Misperceptions and the HIPAA Privacy Rule, Indiana University CLEAR Health Information Continuing Legal Education Program, Health Information and Ethical Representation (December 6, 2012)

Is Return of Individual Research Results Protected Speech Under the First Amendment? Greenwall Foundation Faculty Scholars Program (November 30, 2012)

Biospecimens and Medical Information: Ownership, Access, and Privacy, T.T. Chao Symposium, From Base Pairs to Bedside: What Happens When Genomics-Based Therapies Enter Our Clinics? (October 25, 2012)

Human Subjects Research Regulations: Statutory Constraints on Amendments to the Common Rule, ASLME Health Law Professors' Conference (June 8, 2012)

In Search of Sound Policy on Nonconsensual Uses of Identifiable Health Data,, Petrie-Flom Center, Harvard Law School, Annual Conference: The Future of Human Research Regulation (May 18, 2012)

Fallon Lecture, University of Chicago Center for Health and The Social Sciences (May 14, 2012)

Getting Past the "Terrible Twos" in Health Data Access, Benjamin Cardozo School of Law Symposium, Anonymity and Identity in the Information Age (May 4, 2012)

Informational Research for Medical Product Safety, Indiana University Robert H. McKinney School of Law Symposium, Imagining the Next Quarter Century of Health Care Law (April 12, 2012)

Data Access for 21st-century Biomedical Discovery, New York University School of Law Colloquium on Innovation Policy (February 23, 2012)

Nonconsensual Access to Identifiable Health Data, Association of American Law Schools 2012 Annual Meeting, Joint Session of the Sections on BioLaw and Defamation & Privacy (January 6, 2012)

The U.S. Food and Drug Administration Amendments Act of 2007 and its Impact on Clinical Translation of Pharmacogenomics, University of Toronto Health Law, Ethics and Policy Seminar Series (November 24, 2011)

Proposed Changes to the Common Rule, Texas Medical Center Council of Research Directors Meeting (August 24, 2011)

Panelist, *Control of Patient Data—Health Information Exchanges*, First International Summit on the Future of Health Privacy, Georgetown Law Center (June 13, 2011)

Public Use of Private Health Data, ASLME Health Law Professors' Conference (June 10 – 11, 2011)

Panelist, *Legal & Ethical Obligations*, Clinical Translation of Pharmacogenomics: Management of Incidental Findings and Related Issues, Duke Institute for Genome Sciences & Policy (June 8 – 9, 2011)

Work-in-Progress Presentation, *Data Ownership*, Greenwall Foundation Annual Meeting (May 23, 2011)

Panelist, *Planning Meeting for Summit on the Future of Health Privacy* sponsored by the LBJ School of Public Affairs and Patient Privacy Rights with support of the U.S. Army Telemedicine and Advanced Technology Research Center (November 19-20, 2010)

New Scholars Presentation, Greenwall Faculty Scholars Meeting (November 17 – 19, 2010)

Panelist, *Overview of the Legal & Regulatory Environment,* National Institutes of Health-funded Critical Issues Workshop, Protecting Privacy in Health Research (August 10, 2010)

Panelist, *Alternatives or Supplements to Consent: Existing Regulatory Models,* National Institutes of Health-funded Critical Issues Workshop, Protecting Privacy in Health Research (August 10, 2010)

Panelist, *Ethical Considerations*, National Institutes of Health-funded Critical Issues Workshop,

Protecting Privacy in Health Research (August 10, 2010)

Ethical and Legal Issues in Pharmacogenetic Research and Application, Duke Clinical Research Institute Think Tank: Pharmacogenomics in Cardiovascular Disease: Balancing Scientific Promise with Clinical Reality (August 2, 2010)

Medical Device Legislation and FDA's Regulatory Authority: Legal Authorities to Develop Evidence and Manage Risks in the Postmarket Period for Drugs, 510(k) and PMA Devices, Institute of Medicine Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process (Closed Session, June 27, 2010)

Moving Pharmacogenomics into the Clinic, AARP Board of Directors/Management Retreat, Special Session on Personalized Medicine (June 10, 2010)

Ethical and Privacy Issues in Large Pharmacoepidemiological Data Networks, American Society of Law, Medicine & Ethics Health Law Professors' Conference (June 5, 2010)

Recent Developments in Genetic Screening and Medical Privacy, Annual Convention of TxCOEM, the Texas Chapter of the American College of Occupational and Environmental Medicine (May 21, 2010)

Panelist, *Public Policy Session*, American Society of Clinical Pharmacology and Therapeutics Annual Convention (March 19, 2010)

Pathways for Clinical Translation of Pharmacogenomics after FDAAA, Personalized Medicine in the Clinic, sponsored by Arizona State University/Mayo Clinic/AAAS/Food & Drug Law Institute (March 9, 2010)

Appropriate Human Subject Protections for Research Use of Sentinel System Data, Legal Issues in Active Medical Product Surveillance, convened by the Engelberg Center for Health Care Reform at the Brookings Institution with sponsorship of FDA (March 8, 2010)

Keynote Address: Health Technology, Privacy, and Process, Center for Cybersecurity Research Workshop: A Research Agenda for Privacy and Security of Healthcare Technologies (October 26-27, 2009)

Building Capacity Within Post-FDAAA Data Network Infrastructure, Institute of Medicine Forum on Drug Discovery, Development, and Translation, Community Update: Improving the Science of Drug Safety (September 2, 2009)

Update on Privacy and Governance Issues with FDA's 100-million-person Sentinel Data Network, American Society of Law, Medicine & Ethics Health Law Professors' Conference (June 5, 2009)

Ethical Framework for Pharmacogenomics Implementation (Including Econonomics), Mayo Clinic Pharmacogenetics Research Network Analysis Workshop and Scientific and Steering

Committee Meetings (April 17, 2009)

Panelist, ABA Special Committee on Bioethics and the Law Roundtable on Hot Topics in Bioethics and Law, ABA Midyear Convention (February 14, 2009)

Panelist on Data Network Privacy Issues, FDA Public Workshop (Docket No. FDA-2008-N-0612) Sentinel Initiative: Structure, Function, and Scope (December 16, 2008)

Legal and Ethical Issues in Personalized Medicine: Making Therapies Safe for the Individual Patient Rather than the Average Patient, Houston Bar Association Health Law Section (September 10, 2008)

FDA's Sentinel System for Drug-safety Surveillance, Personalized Therapeutics Seminars, Indiana University School of Medicine (August 5, 2008)

Legal and Regulatory Issues Affecting Clinical Use of Personalized Medicine, American Association for Cancer Research, Translational Medicine 2008 Conference (July 21, 2008)

Pharma-provider Interactions and Ethical Guidelines, University of Houston Continuing Legal Education, Health Care Law (July 10, 2008)

FDA's Sentinel Initiative and Regulation of Medical Products with Predictive and Preventive Uses, American Society of Law, Medicine, and Ethics Annual Health Law Professors' Conference (June 7, 2008)

Ethical and Legal Challenges in Bioengineering, Rice University Lecture Series: New Developments in Bioengineering Technology (March 20, 2008)

Making Personalized Medicine Work: The Legal and Regulatory Paradigm Shift, New York Academy of Sciences, Predictive Toxicology Discussion Group Meeting on Toxicogenomics and Personalized Medicine (Feburary 4, 2008)

Cornerstones of Postmarket Considerations in Personalized Medicine: Label Updates, Surveillance, Clinical Practice, and Legal Liability (panelist), FDA/DIA 4th Annual Pharmacogenomics Workshop (December 11, 1007)

HIPAA Privacy Rule Reform Alternatives for Research Use of Human Biological Materials and Health Data, Roundtable on Personalized Medicine, Privacy, and Ethics (November 7, 2007)

Why Bioethics Fails to Produce Constitutional Rights, American Society of Law, Medicine, & Ethics/Saint Louis University Health Law Scholars Workshop (September 7, 2007)

Interactions Between Medical Product Manufacturers and Health-care Providers (Including Ethical Guidelines), University of Houston Continuing Legal Education, Health Care Law (Dallas, July 12, 2007 and Houston, July 19, 2007)

Use of Genetic Information to Guide Treatment Decisions, American Society of Law, Medicine, and Ethics 30th Annual Health Law Professors' Conference (June 1, 2007)

Individualized Medicine: Ethical Principles and Considerations. Individualized Therapy Lectures, Indiana University School of Medicine (April 13, 2007)

Protecting Patients from Invalid and Excessive Claims in Personalized Medicine, Personalized Medicine and Molecular Diagnostics: Legal, Regulatory, and Ethical Perspectives, Arizona State University (March 2, 2007)

Access to Human Biological Materials and Data in Cancer Research. American Society of Clinical Oncology HIPAA Workshop (February 23, 2007)

Regulatory Barriers to Clinical Introduction of Targeted Cancer Therapies, National Institute of General Medical Sciences, Pharmacogenetics Research Network—Consortium on Breast Cancer Pharmacogenomics Biannual Meeting (November 2, 2006)

Regulatory Barriers to Clinical Introduction of Genetically Targeted Drug Therapies, GenomeCanada International Conference, 2020 Vision: Variation and Function in the Genome (October 25, 2006)

Ethical and Regulatory Issues in New Product Development, Purdue University BIOMEDSHIP Program on Entrepreneurship in Biotechnology (April 20, 2006)

Genetic Studies in Hematological Malignancy: Ethical and Legal Considerations, Horizons in Diagnostics and Therapeutics: Developing Patient-Targeted Therapy, CME Corporate Friday Symposium at 47th American Society of Hematology Annual Meeting (December 9, 2005)

Intellectual Property and Regulatory Issues Affecting Targeted Therapies, Indiana University Department of Medicine, Presentation to Clinical Pharmacology Researchers (May 31, 2005)

Pharmacogenomics and its Implications for the Future of the Health Care Industry, Indiana University Medical Humanities Rounds (April 5, 2005)

Creating Incentives for Genomics Research to Improve Targeting of Therapies, Presentation to Eli Lilly Clinical Research Managerial Personnel (November 23, 2004)

Cultural and Economic Factors in Clinical Ethics, Presentation to Delegation of Japanese Oncologists, The University of Texas M.D. Anderson Cancer Center (May 19, 2004)

Should Prenatal Identification of Inherited Cancer Syndromes be Offered? Multidisciplinary Conference on Parenthood After Cancer: Today's Options and Tomorrow's Hopes, Sponsored by the National Cancer Institute (NCI), National Institute of Child Health and Development, Office of Women's Health at NCI, Office of Women's Health at the Department of Health and

Human Services, and the Lance Armstrong Foundation, held at The University of Texas M.D.

Anderson Cancer Center (March 7, 2004)

Ethical Considerations of Genetic Testing and Screening for Cancer, Institutional Grand Rounds, The University of Texas M.D. Anderson Cancer Center (February, 2004)

Part II: Therapeutic Misconception and the Ethics of Phase I Clinical Trials, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (May 11, 2004) (with co-presenter Valerie Olson of Rice University Department of Anthropology)

Part I: Therapeutic Misconception and the Ethics of Phase I Clinical Trials, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (March 17, 2004) (with co-presenter Valerie Olson)

Emerging Issues in Clinical Application of Genetic Testing, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (January 16, 2004)

Professional Independence and the Ethics of Clinical Ethics Practice, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (December 9, 2003)

Patients' Decision-making Styles and Desire for Information When Making End-of-Life Decisions: Insights from Recent Empirical Studies, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (October 17, 2003)