Breakout Session on
"Addressing Oversight, Governance, & Privacy Issues in Linking Controlled Access Data"
July 28, 2021 – 3:00 – 5:30 p.m. EDT

Panelist Biographies

Cheryl Smith, Ph.D.
Health Science Policy Analyst, Division of Scientific Data Sharing Policy, Office of Science Policy, Office of the Director, National Institutes of Health
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Cheryl Jacobs Smith, Ph.D. is a health science policy analyst in the Office of Science Policy, Office of the Director at the National Institutes of Health. In this role, Dr. Smith is responsible for overseeing the implementation of the trans-NIH Genomic Data Sharing Policy (GDS) and maintaining participant protections and privacy under the Policy in the evolving data science ecosystem. Previous to this position, Dr. Smith was a postdoctoral fellow in the NIH intramural program. There she established foundational research about the positive effects of aspirin in preventing mortality and morbidity among African-American me. Dr. Smith's background includes a Ph.D. in Human Genetics from the University of Michigan in Ann Arbor, MI and a B.S. from Hope College in Holland, MI.

Chris Hammond
Senior Attorney, National Institutes of Health Branch, Public Health Division, Office of the General Counsel, Department of Health and Human Services
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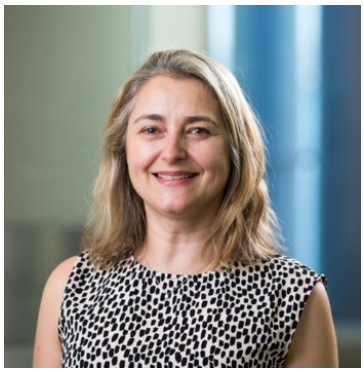
Chris Hammond is a Senior Attorney in the National Institutes of Health Branch, Public Health Division, Office of the General Counsel, Department of Health and Human Services, where he serves as the lead attorney at NIH for legal issues related to privacy, data sharing, data science, public access, and dissemination of clinical trial results information. In addition to advising all of NIH on these issues, Chris is the lead attorney for the *All of Us* Research Program, the National Library of Medicine, and the Office of Data Science Strategy. Chris received his JD from the College of William and Mary School of Law.



Christine Suver Ph.D., PMP
VP, Research Governance & Ethics, Sage Bionetworks
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Christine Suver, vice-president and lead of the Research Governance and Ethics group at Sage Bionetworks. The group develops and pilots creative, participant-centered approaches, standards, and practices that enable open research collaborations, improve research quality and reliability, and empower and protect research participants. We support large research collaborations like the NIH All of Us Research Program (AoURP), various computational analysis contests (DREAM Challenges), and research communities like the Accelerating Medicine Partnership for Alzheimer's Disease or the Human Tumor Atlas Network data coordinating center. We

also design eConsent experiences to better inform research participants and support the autonomous decision of populations with a wide range of memory and cognitive ability (e.g. Alzheimer's Disease Research Center, Parkinson mPower, AoURP). My work focuses on collaborating with stakeholders to develop efficient data sharing governance practices that support the FAIR guiding principles for data stewardship and on addressing the real-world implication of big data analysis and comprehensive data linkage. I co-chair the Governance Working Group of the National COVID Cohort Collaborative initiative (N3C) to enable responsible sharing of clinical data for urgent COVID-related research.

Hyunghoon (Hoon) Cho, Ph.D
Schmidt Fellow, Broad Institute of MIT and Harvard University
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Hoon Cho is a Schmidt Fellow at the Broad Institute of MIT and Harvard. He uses mathematics, cryptography, and machine learning to enhance the information we can gather from massive biomedical datasets. Cho is especially interested in solving problems in the areas of biomedical data privacy, single-cell genomics, and network biology. A key focus of his research is to broaden data sharing and collaboration in biomedical research by developing secure methods for analyzing sensitive data from individuals. He works closely with the Broad's Data Sciences Platform.

Cho received his Ph.D. in electrical engineering and computer science at MIT, advised by Bonnie Berger. He also holds an M.S. in computer science and a B.S. with honors in computer science from Stanford University.

James B. D. Joshi, Ph.D.
Program Director,
Secure and Trustworthy Cyberspace (SaTC), Division of Computer and Network Systems (CNS), Directorate for Computer and Information Science and Engineering, National Science Foundation
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James Joshi is a professor of School of Computing and Information at the University of Pittsburgh, and the director/founder of the Laboratory of Education and Research on Security Assured Information Systems (LERSAIS). He is currently serving as an NSF Program Director in the Computer and Network System (CNS) division and in the Secure and Trustworthy Cyberspace (SaTC) program. He is an elected Fellow of the Society of Information Reuse and Integration (SIRI), a Senior member of the IEEE and a Distinguished Member of the ACM. His research interests include access control models, security and privacy of distributed systems, trust management and secure and privacy-preserving Machine Learning. He is a recipient of the NSF CAREER award in 2006. He has published over 140 articles as book chapters and papers in journals, conferences and workshops, and has served as a special issue editor of several journals including Elsevier Computer & Security, ACM TOPS, Springer MONET, IJCIS, and Information Systems Frontiers. His research has been supported by NSF, NSA/DoD, and Cisco.

Jennifer K. Wagner, JD, PhD
Assistant Professor of Law, Policy, and Engineering, Pennsylvania State University
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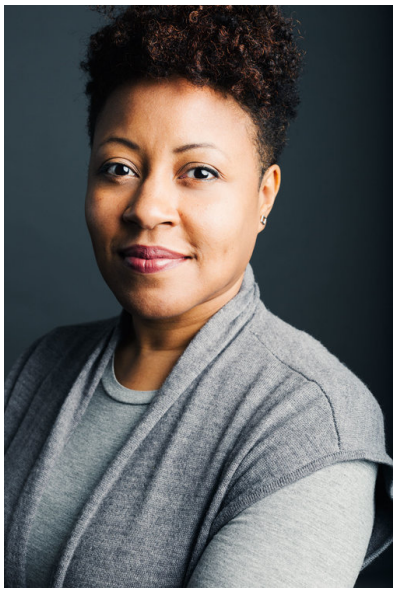
Jennifer K. Wagner, JD, PhD is Assistant Professor of Law, Policy, & Engineering at Pennsylvania State University. Prior to joining Penn State, Dr. Wagner conducted ELSI research at Duke University's Institute for Genome Sciences & Policy, the University of Pennsylvania's Center for the Integration of Genetic Healthcare Technologies, and Geisinger's Center for Translational Bioethics & Health Care Policy. As a 2014-2015 AAAS Science & Engineering Congressional Fellow, she assisted with science and privacy policy issues in a US Senator's office. She is former chair of the ASHG Social Issues Committee (now known as the Professional Practice and Social Implications Committee), former co-chair of the Ethics Committee for the American Association of Biological Anthropologists, current member of the Pennsylvania Bar Association's Cybersecurity & Data Privacy Committee, and a member of the Scientific Advisory Board for Sage Bionetworks. Dr. Wagner's research has been focused on the international human right to science, including human-centered design and matters of nondiscrimination, privacy, and equity with genetic/omic and mobile health technologies. She has been a key contributor to Geisinger's Data Ethics Work Group and has led relevant research on the gap between what HIPAA allows and public perceptions of what HIPAA allows. Additionally, Dr. Wagner recently led an NIDCR/OD-funded supplemental ELSI project focused on facial imaging and other biometric data; leads an NHGRI-funded R01, "Consumer Protections for Genomics & Precision Health;" and leading a legal research aim in an NCI-funded study to examine how privacy laws facilitate or hinder notification of at-risk relatives in genetic cascade/traceback programs. During Geisinger's involvement with the All of Us Research Program, Dr. Wagner contributed to several working groups, including those focused on informed consent, privacy and security, participant-provided information, and engagement/communication. She can be found on Twitter as @DNAlawyer; by email at jkw131@psu.edu; and by phone at 814-689-9680.



Kadija Ferryman, PhD
Assistant Professor, Johns Hopkins Berman Institute of Bioethics and Department of Health Policy and Management Bloomberg School of Public Health Johns Hopkins University
kferrym1@jhmi.edu

Dr. Kadija Ferryman is a cultural anthropologist who studies the social, cultural, and ethical implications of health information technologies. Specifically, her research examines how genomics, digital medical records, artificial intelligence mediate the production of social difference and racial disparities in health. She is currently Assistant Professor at the Johns Hopkins Berman Institute of Bioethics and the Department of Health Policy and Management at the Bloomberg School of Public Health at Johns Hopkins University. She completed postdoctoral training at the Data & Society Research Institute in New York, where she led the Fairness in Precision Medicine research study, which examined the potential for bias and discrimination in predictive precision medicine.
She earned a BA in Anthropology from Yale University, and a PhD in Anthropology from The New School for Social Research. Before completing her PhD, she was a policy researcher at the Urban Institute where she studied how housing and neighborhoods impact well-being, specifically the effects of public housing

redevelopment on children, families, and older adults. Dr. Ferryman is a member of the Institutional Review Board for the All of Research Program, a Mozilla Open Science Fellow, and an Affiliate at the Center for Critical Race and Digital Studies. She has published research in journals such as *Journal of the American Medical Informatics Association*, *Paediatric and Perinatal Epidemiology*, the *Journal of Health Care for the Poor and Underserved*, *European Journal of Human Genetics*, and *Genetics in Medicine*. Dr. Ferryman's research has been featured in multiple publications including Nature, STAT, and The Financial Times.

Katherine Blizinsky, Ph.D
Policy Director, *All of Us* Research Program, NIH
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Katherine Blizinsky, Ph.D., is the Policy Director for the *All of Us* Research Program, leading program policy activities—including legislative and regulatory policy analysis—and the development and strategic visioning for work regarding ethical, legal, and social implications (ELSI). Dr. Blizinsky has policy experience with both the legislative and executive branches. On Capitol Hill, she worked with the Senate Health, Education, Labor, and Pensions Committee under Ranking Member Patty Murray, where, among other roles, she helped lead the drafting and negotiation of key provisions of the 21st Century Cures Act. Her work at *All of Us* has drawn on her expertise in the areas of participant protections; data privacy, access, and use models; informed consent; genomics; and the ethical conduct of research. A neuroscientist and geneticist, specializing in research on mental health and cognition, with focuses on health equity and gene-environment interaction, Dr. Blizinsky continues to be involved in academic research and lectures frequently on genomics, neuroscience, policy, and ELSI.

Kayte Spector-Bagdady JD, Mbioethics
Assistant Professor of Obstetrics & Gynecology,
Associate Director of the Center for Bioethics & Social Sciences in Medicine, University of Michigan Medical School
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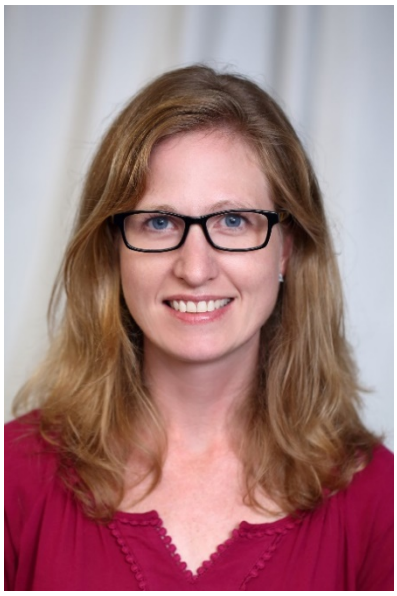
My research focuses on the ethics and regulation of secondary research use of health data and human biospecimens and I have published relevant pieces in The New England Journal of Medicine, Science, Nature Medicine, and USA Today, among others.

My work on datasharing been funded by the National Human Genome Research Institute, the National Cancer Institute, the Greenwall Foundation, and the National Center for Advancing Translational Sciences. I currently hold an NIH Career Development Award studying the genetic data-sharing market with a focus on agreements between private industry and academic medical centers. At U-M, I Chair the Research Ethics Committee and am the ethicist on the Michigan Medicine Human Data and Biospecimen Release Committee. I was also the Associate Director for President Obama's Bioethics Commission and staff lead author on the report focusing on emerging genetic and data technologies. I am a former practicing FDA attorney.



Kerry Goetz, MS
Associate Director, National Eye Institute, Office of Data Science and Health Informatics
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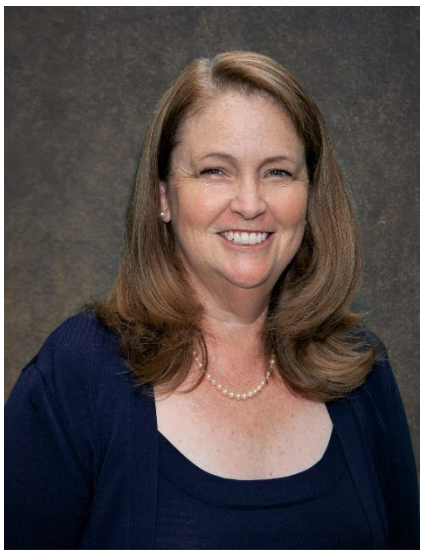
Kerry Goetz is the Associate Director for the National Eye Institute's Office of Data Science and Health Informatics. In this capacity she is responsible for advancing data management and sharing strategies to make NEI data FAIR (Fully AI-Ready & Findable, Accessible, Interoperable, and Reusable). For over a decade, Kerry has been leading the eyeGENE Program, a controlled access resource with data, samples, and a patient registry for rare eye conditions. She has implemented sharing of several other clinical trial datasets through NEI BRICS, part of the NEI Data Commons. Kerry has also been entrenched in standards development through the NIH CDE Task Force since 2011 and has worked closely with LOINC to create and review ophthalmology codes.



Laura Lyman Rodriguez, Ph.D.
Interim Chief Program Support Officer and a *Senior Advisor to the Executive Director*, Patient Centered Outcomes Research Institute (PCORI)
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Laura Lyman Rodriguez, Ph.D., is the Interim Chief Program Support Officer and a Senior Advisor to the Executive Director at the Patient-Centered Outcomes Research Institute (PCORI). As the Interim Chief Program Support Officer, Dr. Rodriguez leads the integration of key operational services that support PCORI's programs, including merit review, contracts management, and the information and systems management needed to support the integrity of these activities. Prior to joining PCORI, she spent more than 16 years at the National Human Genome Research Institute at the National Institutes of Health (NHGRI, NIH). In addition to her work at NHGRI to advance policies and outreach activities to promote the understanding of and participation in genomic science and the emerging clinical applications of genomic tools and information, Laura was a primary leader for the development and agency-wide implementation of NIH genomic data sharing policies. In this latter capacity, Dr. Rodriguez designed governance and implementation approaches to anticipate and meet evolving research opportunities as well as researchers' ethical and legal obligations to respect and protect research participant interests and maximize the public benefit possible through responsible and appropriate data management, access, and use.

Lucila Ohno-Machado, M.D., MBA, Ph.D.
Professor and Chair, UC San Diego Health Department of Biomedical Informatics; *Associate Dean* for Informatics and Technology
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Lucila Ohno-Machado, MD, MBA, PhD received her medical degree from the University of São Paulo and her doctoral degree in medical information sciences and computer science from Stanford. She is Associate Dean for Informatics and Technology, and the founding chair of the UCSD Health Department of Biomedical Informatics at UCSD, where she leads a group of faculties with diverse backgrounds in medicine, nursing, informatics, and computer science. Prior to her current position, she was faculty at Brigham and Women's Hospital, Harvard Medical School and affiliated with the MIT Division of Health Sciences and Technology. Dr. Ohno-Machado is an elected member of the American College of Medical Informatics, the American Institute for Medical and Biological Engineering, the American Society for Clinical Investigation, and the National Academy of Medicine. She served as editor-in-chief for the Journal of the American Medical Informatics Association from 2011 to 2018. She directs the patient-centered Scalable National Network for Effectiveness Research, a large clinical data research network covering more than 30 million patients and 12 healthcare systems and was one of the founders of UC-Research exchange, a clinical data research network that connected the data warehouses of the five University of California medical centers. She was the director of the NIH-funded National Center for Biomedical Computing dash (integrating Data for Analysis, 'anonymization,' and Sharing) based at UCSD with collaborators in multiple institutions, as well as other NIH-funded consortia and research projects. Her research focuses on privacy-preserving distributed analytics for healthcare and biomedical sciences. She has received numerous awards for innovations in biomedical informatics.

Melissa Basford, MBA
Sr. Director, Big Data Support Services, Vanderbilt University Medical Center, Vanderbilt Institute for Clinical and Translational Research (VICTR)
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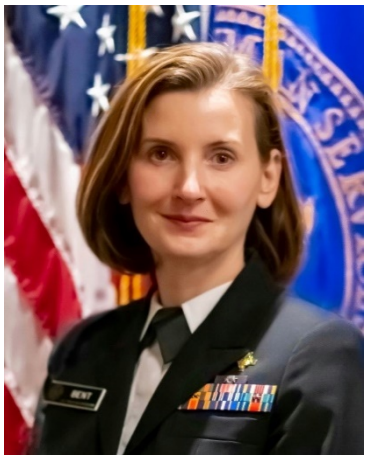
I am the Senior Director for Big Data Support Services for the Vanderbilt Institute for Clinical and Translational Research (VICTR). In my role I lead a team responsible for developing and supporting large data and bio-sample resources for use in research and for participating in national and international efforts to advance science using those resources. I have 20+ years of experience in the healthcare industry, health research, technology operations, project management and systems design. I work with interdisciplinary experts and teams on issues key to data sharing, including data access models in high compute environments, participant and patient privacy, cybersecurity, and data utility for health research. I am the Program Manager for Vanderbilt's Synthetic Derivative database (Vanderbilt's de-identified electronic medical record), a pioneering example of sharing data and decreasing researcher burden while preserving privacy, and the Research Derivative (identified data repository). I am the Director of Product and Operations for the *All of Us Research Program's* Data and Resource Center, located at Vanderbilt University Medical Center. In that role I have served in key roles supporting the novel data access model for the All of Us Research Hub and Researcher Workbench.

Pamela Gavin
Executive Vice President, NORD
Pamela Gavin sets the strategic direction for National Organization for Rare Disorders (NORD) and implements programs and services that provide innovative solutions to address the needs of the rare disease community. She is responsible for bringing together all stakeholders within the rare disease space and works closely with NORD's board of directors, donors, corporate council and member organizations, other partners, and staff. Prior to joining NORD in 2010, Pam spent 13 years executing complex, multi-stakeholder programs aimed at improving healthcare safety. As a consultant to the federal government, she implemented a new web-based portal for reporting pre-market and post-market safety data to Food and Drug Administration (FDA) and National Institutes of Health (NIH), for which she received Special Citations from the FDA Commissioner and Director of the Center for Food Safety and Applied Nutrition (CFSAN) for outstanding leadership and teamwork.

Paul Harris, Ph.D., FACMI, FIAHSI
Director, Office of Research Informatics; *Professor,* Department of Biomedical Informatics, Vanderbilt University Medical Center
paul.a.harris@vumc.org

Paul A. Harris, PhD, is a professor of Biomedical Informatics with secondary appointments in Biostatistics and Biomedical Informatics. Dr. Harris serves as Director of the Vanderbilt University Medical Center Office of Research Informatics and in this role created the REDCap data platform that has been broadly adopted by more than 5,000 institutional partners and 1.8 million end-users across 141 countries. He also created a national recruitment registry, ResearchMatch, that matches individuals across the USA with research teams recruiting patients for studies and trials. Dr. Harris received a PhD degree in biomedical engineering from Vanderbilt University and has significant experience working in the field of clinical and translational research informatics. He is an elected fellow in the American College of Medical Informatics (ACMI) and in the International Academy of Health Sciences Informatics (IAHSI). Dr. Harris is a recipient of the Donald A.B. Lindberg Award for Innovation in Informatics, an American Medical Information Association (AMIA) signature award recognizing innovation in the field of informatics that has dramatically moved or changed the field.

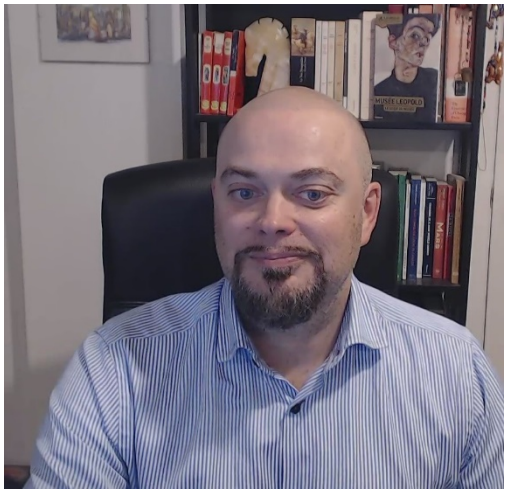


Robyn Bent, RN, MS
Director, Patient Focused Drug Development Program, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
PatientFocused@fda.hhs.gov

Robyn Bent joined the US FDA in 2019 as the director of the Patient-Focused Drug Development (PFDD) Program in the Center for Drug Evaluation and Research (CDER). PFDD is an effort to systematically obtain patient input and facilitate the incorporation of meaningful patient input into drug development and regulatory decision making. The PFDD initiative includes the CDER Standard Core Clinical Outcomes Assessments and Endpoints Pilot Grant Program which provides avenues to advance the use of patient input as an important part of drug development. Prior to joining FDA, Robyn held several positions at the National Institutes of Health. Captain Bent has extensive experience in clinical trial design, conduct, and oversight. Robyn earned her Bachelor of Science in Nursing from The Catholic University of America and her Master of Science degree from the George Washington University.

Sharon Terry
Chief Executive Officer, Genetic Alliance
sterry@geneticalliance.org

My work on our Promise for Engaging Everyone Responsibly (PEER) – a platform that gives ordinary people, their families, and communities, the tools they need to share patient reported outcomes, electronic health records, genetic and genomic information. Individuals always keep a string on their data, and control access to it. They are given shares in the company, and in fact own, the company LunaDNA, as a result of their sharing.



Yann Joly, Ph.D. (DCL), FCAHS, Ad.E.
Research Director, Centre of Genomics and Policy, McGill University
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Yann Joly, Ph.D. (DCL), FCAHS, Ad.E. is the Research Director of the Centre of Genomics and Policy (CGP). He is an Associate Professor at the Faculty of Medicine, Department of Human Genetics cross-appointed at the Bioethics Unit, at McGill University. Prof. Joly is the Chair of the Bioethics Workgroup of the International Human Epigenome Consortium (IHEC) and Co-Lead the regulatory and ethics work stream of the Global Alliance for Genomics and Health (GA4GH). He was Chair (2017-2019) of the Ethics and Governance Committee of the International Cancer Genome Consortium (ICGC).

Prof. Joly's research interests lie at the interface of the fields of medical research, big data, and public policy. He created the first international genetic discrimination observatory (GDO https://gdo.global/en/gdo-description) in 2018. He has published his findings in over 180 peer-reviewed articles featured in top legal, ethical, and scientific journals.