



## The Ethics of Data Access, Use, and Sharing for Human Subjects Research

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### Biographies

**Ifeoma Ajunwa, JD, PhD**, Fellow at the Berkman Klein Center at Harvard University. She holds a doctorate from Columbia University and was previously a practicing attorney. She has published extensively on health law and health data, particularly in regards to issues arising in the workplace. Her most recently paper on workplace wellness programs was published by the *Harvard Business Review*. She also wrote the first comprehensive ethical framework for workplace wellness programs' handling of health data. Another article on the protection of employee's health data, "Limitless Worker Surveillance" is forthcoming from the *California Law Review* and was endorsed by the NYTimes Editorial Board. Her opinions and commentary on health issues have been featured in the *NY Times*, *the Guardian*, CNN, Bloomberg, and other major media outlets. Dr. Ajunwa has presented her research before the EEOC, the CFPB, and was a keynote speaker for the 2016 Patient Privacy Rights Summit. Dr. Ajunwa will be speaking on worker's health privacy at the SXSW Festival in March of 2017. Her forthcoming book, "The Quantified Worker" will be published by the Cambridge University Press.

**Albert J. "A.J." Allen, MD, PhD**, is currently a senior medical fellow in the Medicines Development Unit at Eli Lilly and Company, where he is the medical lead for pediatric drug development efforts across all therapeutic areas.

A native of Iowa, Dr. Allen received an SB in chemistry and an MS in biochemistry from the University of Chicago in 1980, followed by an MD and PhD in pharmacology from the University of Iowa in 1988. From 1988 to 1995 he completed residencies in psychiatry and child psychiatry at Iowa, and a research fellowship in child psychiatry at NIMH. From 2011 to 2013 he was the chair of Lilly's Bioethics Advisory Committee. From 2011 to 2015 he was a member of SACHRP and SACHRP's Subcommittee on Harmonization (SoH).

In 2013 Dr. Allen was diagnosed with an early, stage 1 multiple myeloma for which he underwent an autologous stem cell transplant. Currently in remission, his experiences and perspective as a patient have influenced his views on clinical research and bioethics.

For him, bioethics is critical to enabling research subjects to feel they are treated fairly, respected and protected. Dr. Allen serves on PRIM&R's Board of Directors and the Public Policy Committee.

**Mark Barnes, JD**, Faculty Co-Director & Co-Chair, Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard University (MRCT Center), Partner, Ropes & Gray LLP, Lecturer, Yale School of Medicine; Visiting Lecturer, Yale Law School. Mark's law practice and his teaching at

Yale focus on health care law and finance, human and animal research, stem cell and genetic research, research grants and contracts, research misconduct, and international research. Mark formerly served at Harvard as the Senior Associate Provost and University Senior Research Officer and started and directed Harvard's HIV/AIDS treatment programs in Nigeria, Tanzania and Botswana. He serves on the Ethics Working Group of the NIH's HIV Prevention Trials Network (HPTN) and is the ethics advisor to HPTN Trial O71 in South Africa and Zambia. Mark has held senior appointed positions in the New York City and State departments of health.

**John R. Baumann, PhD**, Associate Vice President for Research Compliance at Indiana University, including both the Bloomington and Indianapolis campuses as well as the five regional campuses and several local hospitals. He earned his Ph.D. in Sociology from the Graduate Center of the City University of New York.

Dr. Baumann has over 25 years of experience in research, research administration, responsible conduct of research and research compliance. He has had direct line responsibility for research development, coordination and submission of grant and contact applications, management of funded research as well as compliance with regulations and ethical standards for human subjects research, research with animals, conflict of interest, and radiation/biological safety. He has been directly involved in the administration of research at all levels and is sensitive to the administrative responsibilities and burdens placed on both the researcher(s) and the institution.

In addition, he serves as a member of Council of Accreditation and a site visitor for AAHRPP and chairs the social-behavioral IRBs of National Development and Research Institutes (NDRI) and American Academy of Family Physicians. Prior to joining IU, Dr. Baumann was Vice Provost for Research at University of Missouri – Kansas City and Deputy Executive Director of NDRI.

**Elizabeth Buchanan, PhD**, Endowed Chair in Ethics and Director of the Center for Applied Ethics at the University of Wisconsin-Stout. She is serving as director of research administration on an interim basis, where she is responsible for overseeing IRB, IACUC, research misconduct, and grants and contracts.

Elizabeth's research focuses on the intersection of research regulations and internet research. She has written and presented widely for over fifteen years to the Secretary's Advisory Committee to the Office for Human Research Protections, many IRBs throughout the country, and research ethics boards internationally. Elizabeth was a primary contributor to the SACHRP Recommendations on Internet Research as well as primary co-author of the Association of Internet Researchers Ethics Guidelines for Internet Research. Elizabeth has been involved with PRIM&R and served as faculty and on conference planning committees since 2008, and was elected to the Board of Directors in 2016. Elizabeth has also been a member of the American Association for the Advancement of Science Committee on Scientific Freedom and Responsibility since 2012. Additionally, Elizabeth is currently PI on her fourth National Science Foundation grant.

She holds BA degrees from Rutgers University, and her MA and PhD from the University of Wisconsin-Milwaukee.

**Alex Capron, LLB**, holds the rank of university professor at the University of Southern California (USC), where he occupies the Scott H. Bice Chair in Healthcare Law, Policy and Ethics and serves as Vice Dean for Faculty and Academic Affairs at the Gould School of Law, and as Professor of Medicine and Law at the Keck School of Medicine; co-directs USC's Pacific Center for Health Policy and Ethics; and leads the Research Ethics Program of the Southern California Clinical and Translational Science

Institute. From 2002 to 2006, he was the first director of Ethics, Trade, Human Rights, and Health Law at the WHO in Geneva, and from 1979 to 1983 he was the executive director of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Professor Capron is an elected member of the National Academy of Medicine and of the American Law Institute, a founding fellow of The Hastings Center, and a fellow of the American Association for the Advancement of Science. He has been president of the International Association of Bioethics and of the American Society of Law, Medicine and Ethics. He is the Immediate Past Chair of the PRIM&R Board of Directors, on which he continues to serve, and is a member of its Public Policy Committee.

**Neal Dickert, MD, PhD**, Assistant Professor of Medicine in the Division of Cardiology, Emory University School of Medicine. He also holds a secondary appointment in the department of epidemiology at the Rollins School of Public Health and is a senior faculty fellow at the Emory Center for Ethics. Dr. Dickert is a board-certified cardiologist and researcher whose scholarly activities are focused primarily on ethical issues in clinical research. He has led and participated as an investigator in multiple research projects funded by NIH, PCORI, and the Greenwall Foundation. He has published work and has ongoing projects related to optimizing approaches to consent in the context of acute care research and to conducting research under an exception from informed consent in emergency settings. Other areas of interest and scholarship include the use of incentives in clinical research, the conduct of research in the developing world, and the process of shared decision-making in cardiovascular disease. Dr. Dickert is a former fellow in the Department of Bioethics at the NIH, a past recipient of the Pillars of PRIM&R Award, and an alumnus of the Greenwall Foundation Faculty Scholar Program.

**Susan S. Fish, PharmD, MPH**, is professor of biostatistics and epidemiology at the Boston University School of Public Health. Dr. Fish received her Doctor of Pharmacy degree from the University of Minnesota, a Masters of Public Health from Boston University, a bachelor's Degree in pharmacy from Massachusetts College of Pharmacy and Allied Health Sciences, and a bachelor's degree in chemistry and education from the University of Massachusetts. Dr. Fish previously held positions as director of human subjects protection and associate director of the Office of Clinical Research at Boston University Medical Center (BUMC), director of the BUMC IRB, director of research participant safety at the General Clinical Research Center at Boston University School of Medicine (BUSM), director of the Masters in Clinical Investigation Program at BUSM, director of regulatory affairs at CareStat, Inc, vice chair for research in the department of emergency medicine at Boston City Hospital/Boston Medical Center, associate professor of emergency medicine at BUSM, associate director of the Massachusetts Poison Control System, and associate professor at Massachusetts College of Pharmacy and Allied Health Sciences. She was a member of the Human Studies Committee at Boston City Hospital/Boston Medical Center from 1989-99 and served for five years as associate chair of the Committee.

**Celia B. Fisher, PhD**, is the Marie Ward Doty University Chair in Ethics, Professor of Psychology, founding Director of the Fordham University Center for Ethics Education and Director of the NIDA-funded HIV and Drug Abuse Prevention Research Ethics Training Institute. She has chaired the American Psychological Association's Ethics Code Task Force, the Environmental Protection Agency's Human Studies Review Board, and the DHHS Secretary's Advisory Committee on Human Research Protections Subcommittee on Children's, Research, and the American Public Health Ethics Code Revision Task Force and has served on several Institute of Medicine and other national committees on human research protections. Dr. Fisher is the author of *Decoding the Ethics Code: A Practical Guide for Psychologists* (4th Edition, 2017), 8 edited volumes and over 170 publications. Her federally funded

research programs applies her Goodness-of-Fit ethical framework to creating an empirical basis for ethical decision making in research involving vulnerable populations, including ethnic minority youth and families, pediatric oncology patients, sexual and gender minority youth, active drug users, and adults with impaired consent capacity. She was awarded the Lifetime Achievement Award for Excellence in Human Research Protection in 2010 and was named a 2012 Fellow of the American Association for the Advancement of Science.

**Leonard Glantz, JD**, is a professor emeritus of health law, bioethics, and human rights at the Boston University School of Public Health. Professor Glantz has spent much of his career examining issues related to the protection of human subjects. He is the author of numerous books, articles, reports, and appellate briefs on medico-legal issues. He is the author or editor of two books, *Informed Consent to Human Experimentation: The Subject's Dilemma*, with George Annas and Barbara Katz (1977), and *Children as Research Subjects: Science, Ethics and Law*, co-edited with Michael Grodin (1994). He has been an IRB member for more than 30 years. His current research interests include reproductive rights, rights of the terminally ill, regulation of research with human subjects, children's rights, and the constitutional limits of public health regulation. Mr. Glantz is a former PRIM&R board member and is currently a member of PRIM&R's Public Policy Committee.

**Christine Grady, MSN, PhD**, chief of the Department of Bioethics at the National Institutes of Health Clinical Center. Her research focuses on the ethics of clinical research, especially subject recruitment, incentives, vulnerability, informed consent, and international research ethics. She is a senior research fellow at the Kennedy Institute of Ethics and an elected fellow at the Hastings Center and the American Academy of Nursing. She also served as a member of the Presidential Commission for the Study of Bioethical Issues. Dr. Grady has authored more than 100 papers, authored or edited several books, and has lectured widely on ethical issues in clinical research and clinical care, HIV disease, and nursing. She is an attending on the Bioethics Consultation service, an IRB and DSMB member, and a member of several editorial boards. She holds a BS in nursing and biology from Georgetown University, a MSN in community health nursing from Boston College, and a PhD in philosophy from Georgetown University. In addition to being the vice chair of PRIM&R's Board of Directors, Christine serves as a member of the Public Policy Committee. Dr. Grady is serving in her personal capacity.

**Karen Hansen** is Director of the Institutional Review Office (IRO) at the Fred Hutchinson Cancer Research Center, Seattle, Washington, USA. She was a co-founder of the Collaborative Institutional Training Initiative ([www.citiprogram.org](http://www.citiprogram.org)) in 2000 and was awarded the Applied Research Ethics National Association's Distinguished Service Award in 2001. She currently serves on the Board of Directors of Public Responsibility in Medicine and Research; the External Advisory Board for the Collaborative Institutional Training Initiative; and, the planning committee of the National Comprehensive Cancer Network's ([www.nccn.org](http://www.nccn.org)) IRB Directors Forum.

**Brian Herman, MD**, Professor of Biomedical Engineering at University of Minnesota. Dr. Herman is a two time NIH MERIT Award winner whose scientific career has examined the relationship of apoptosis and aging. His work centers on the potential role for caspase-2 in oxidative injury, apoptotic cell death and aging. He has demonstrated a critical role for caspase-2 in maintaining bone homeostasis, that caspase-2 is an endogenous repressor of autophagy, and that caspase-2 exists in the mitochondria and is essential for mitochondrial oxidative stress-induced apoptosis.

In addition, Dr. Herman has served as Vice President for Research at UT Health in San Antonio, Texas and until December 31, 2016, at the University of Minnesota. Over the past two years, the University of Minnesota undertook a rigorous review and assessment of its human research policies and practices. Based on that review, the University is now implementing major changes to enhance its

human research protection program. The Advancing Human Research Protections initiative aims to strengthen protections for human research participants and establish a program that will serve as a national model. Key enhancement areas include renewing our commitment to research ethics, more education and training for investigators and staff, changes to Institutional Research Board (IRB) processes and policies, new approaches for managing conflicts of interest, and increased community participation and oversight. More information about this initiative can be found at [advance-hsr-alerts.umn.edu](http://advance-hsr-alerts.umn.edu).

**Adrian F. Hernandez, MD, MHS, FAHA**, Professor of Medicine at Duke University Medical Center, Director, Health Services and Outcomes Research, Faculty Associate Director at Duke Clinical Research Institute. Dr. Hernandez is a cardiologist with extensive experience in clinical research ranging from clinical trials to outcomes and health services research. He is the Director of Health Services and Outcomes Research and an Associate Director of the Duke Clinical Research Institute. He leads research programs focused on understanding population health, generating real-world evidence and improving patient-centered outcomes through development of new therapies or better care delivery in our national health system. He is the Coordinating Center Principal Investigator for multiple networks and clinical trials such as the NHLBI's Heart Failure Research Network, PCORI's National Patient-Centered Clinical Research Network (PCORnet) and NIH's Health System Collaboratory. A central aim of these networks is to transform clinical research by uniting patients, clinicians, health systems and electronic health data to improve population health and decision making. Dr. Hernandez has over 350 published articles in high-tier journals including the *New England Journal of Medicine*, *Journal of the American Medical Association*, and *Lancet*.

**Elisa A. Hurley, PhD**, is the executive director of Public Responsibility in Medicine and Research (PRIM&R), an international nonprofit organization dedicated to advancing the highest ethical standards in the conduct of biomedical and social science research through education, membership services, professional certification, public policy initiatives, and community building. As chief executive, Elisa leads the organization in the execution of its mission and has overall strategic and operational responsibility for PRIM&R's staff, programs, and organizational relationships. Elisa is a moral philosopher by training. Prior to arriving at PRIM&R in 2010, she was an assistant professor of philosophy at The University of Western Ontario. Elisa received a BA in philosophy from Brown University, a PhD in philosophy from Georgetown University, and held a Greenwall Fellowship in Bioethics and Health Policy at the Johns Hopkins Berman Institute of Bioethics and Georgetown University's Kennedy Institute of Ethics. Elisa's recent scholarly work includes co-authoring a chapter on the history of biospecimen research in *Specimen Science: Ethics and Policy Implications* (MIT press, forthcoming spring 2017), and a chapter on the past and present of human subject protections in *Human Subjects Research Regulation: Perspectives on the Future* (MIT Press, 2014).

**Martha F. Jones, MA, CIP**, Executive Director of the Human Research Protection Office (HRPO) at Washington University in St. Louis. Ms. Jones is a member of the CTSA Clinical Trials Task Force, the EPIC implementation team, the OnCore Steering Committee, the Research Administration IT Governance Group, and an IRB member. Ms. Jones also leads the IT development team for the "myIRB" database and application system, a system she co-developed at The University of Iowa. She has a background in clinical research ethics, epidemiology, biostatistics, speech pathology, audiology, public health and the coordination multicenter research studies.

Ms. Jones is a member of the Council on Governmental Relations (COGR) Research and Regulatory Reform Subcommittee, the SMART IRB Harmonization Steering Committee, and co-leads the National Comprehensive Cancer Centers (NCCN) IRB Directors group. She serves on the Council for

the Association for the Accreditation of Human Research Protection Programs (AAHRP), the AAHRPP IRB Reliance Working Group, and is a Site Visit Team Leader.

Ms. Jones was previously the manager for the Clinical Trials Statistical and Data Management Center, Deputy Director of the Center for Public Health Statistics and an IRB Chair and IRB Director at Iowa. She also co-directed a course in Clinical Research Ethics.

**Nancy Kass, ScD**, is the Phoebe R. Berman Professor of Bioethics and Public Health at Johns Hopkins, Deputy Director for Public Health in the Berman Institute of Bioethics, and Professor in the JHU Bloomberg School of Public Health. In 2009-2010, Dr. Kass was based in Geneva, Switzerland, working with the World Health Organization (WHO) Ethics Review Committee Secretariat. Current research examines informed consent in randomized trials, ethics in international health research, ethical guidance development for infectious outbreaks, and ethics and learning health care. Dr. Kass directed the School's PhD program in bioethics and health policy from its inception until 2016, and she directs the Johns Hopkins Fogarty African Bioethics Training Program. She served as consultant to the President's Advisory Committee on Human Radiation Experiments, the National Bioethics Advisory Commission, and the National Academy of Sciences. Dr. Kass is an elected member of the Institute of Medicine and elected Fellow of the Hastings Center.

**Susan Z. Kornetsky, MPH**, is the senior director of clinical research compliance at Boston Children's Hospital. She has experience in the following: Directing an IRB administrative office, educating principal investigators regarding IRB regulations, assisting investigators with protocol development, assuring institutional compliance with all federal and state regulations pertaining to human research, establishing appropriate policies and procedures, and overseeing a quality improvement program for human research protections. Ms. Kornetsky has served on the SACHRP Subcommittee on Children, and currently serves on the SACHRP Subpart A Subcommittee. She is a past board member and site visitor for AAHRPP, as well as a former member of the IOM's Committee on Clinical Research Involving Children. She lectures at many national meetings, in addition to PRIM&R's conferences and educational programs. She is faculty for educational programs run internationally through Harvard Medical School Office of Global education and is a faculty member for a Fogarty international grant. Ms. Kornetsky is the chair of PRIM&R's Board of Directors.

**Rebecca Li, PhD**, Executive Director, Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard University (MRCT Center), Instructor in Medicine and the Center for Bioethics, Harvard Medical School. Dr. Li has over 17 years of experience spanning the entire drug development process with experience in Biotech, Pharma and CRO environments. Dr. Li has served as the Executive Director of the Multi-regional Clinical Trial Center at Harvard since 2012. The Center was chartered to improve the integrity, safety and rigor of global clinical trials. She currently is an Instructor in Medicine in the Division of Global Health Equity, Department of Medicine in the Harvard Medical School and teaches Research Ethics at the Center for Bioethics. She completed a Fellowship in 2013 in the Division of Medical Ethics at Harvard Medical School. Prior to joining Harvard, Dr. Li served as the VP of Clinical Research at the New England Research Institutes for 6 years. She was also previously employed at Wyeth Research as the Associate Director in Translational Clinical Research. She earned her PhD in Chemical and Biomolecular Engineering from Johns Hopkins University.

**Elizabeth Loder, MD, MPH**, head of research for *The BMJ* and a Professor of Neurology at Harvard Medical School. At *The BMJ*, she supervises an international team of editors who evaluate and select the research papers published in the journal. In addition to her work for *The BMJ*, Dr. Loder is an associate editor for the journals *Headache* and *Cephalalgia*. She also serves as Chief of the Division of Headache in the Department of Neurology at the Brigham and Women's Hospital in Boston.

Dr. Loder earned an AB in Biology from Harvard College, an MD from the University of North Dakota Medical School, and a master's degree in Public Health from the University of Massachusetts, Amherst. She is board certified in Internal Medicine and is certified in Headache Medicine by the United Council for Neurologic Subspecialties.

Dr. Loder is a past president of the American Headache Society. She has extensive experience as a clinical investigator in clinical trials of treatments for migraine and other headache disorders. She speaks regularly at regional, national and international medical meetings on topics related to pain and headache as well as publication practices and ethics.

**Deven McGraw, MPH, JD**, is the Deputy Director for Health Information Privacy at the HHS Office for Civil Rights (OCR). She is a well-respected expert on the HIPAA Rules and has a wealth of experience in both the private sector and the non-profit advocacy world. Prior to joining OCR, she was a partner in the healthcare practice of Manatt, Phelps & Phillips, LLP. She previously served as the Director of the Health Privacy Project at the Center for Democracy & Technology, a leading consumer voice on health privacy and security policy issues, and as the Chief Operating Officer at the National Partnership for Women & Families, where she provided substantive policy expertise for the Partnership's health policy agenda. Ms. McGraw spearheads OCR's policy, enforcement, and outreach efforts on the HIPAA Privacy, Security, and Breach Notification Rules and leads OCR's work on Presidential and Departmental priorities on health privacy and security. She graduated magna cum laude from the University of Maryland. She earned her J.D., magna cum laude, and her L.L.M. from Georgetown University Law Center and was Executive Editor of the *Georgetown Law Journal*. She has a Master of Public Health from Johns Hopkins School of Hygiene and Public Health.

**Laura Odwazny, MA, JD**, is a Senior Attorney with the Office of the General Counsel, U.S. Department of Health and Human Services. Ms. Odwazny's primary client is the Office for Human Research Protections, which interprets and enforces the HHS protection of human subjects regulations. Ms. Odwazny also currently advises the Presidential Commission for the Study of Bioethical Issues and the HHS Office of Global Affairs. Throughout her 16 years with the Office of the General Counsel, Ms. Odwazny also has provided legal advice to various other agencies within HHS. Ms. Odwazny is a graduate of the University of Chicago and the University of Pittsburgh School of Law, and received a M.A. in Bioethics through the History and Philosophy of Science Department at the University of Pittsburgh. Ms. Odwazny served as an adjunct professor at American University Washington College of Law, teaching "The Law and Ethics of Human Subjects Research," and currently is an adjunct professor in the University of Pittsburgh School of Law Health Care Compliance Certificate program, teaching "Compliance in Research." Ms. Odwazny has served on the Core Conference Planning Committee of the Public Responsibility in Medicine & Research (PRIM&R) Advancing Ethical Research conference since 2013 and is the committee co-chair.

**Sally Okun, RN, MMHS**, is the Vice President for Advocacy, Policy and Patient Safety at PatientsLikeMe, an online patient research network. She is responsible for bringing patient voice and insight to diverse advocacy and health policy discussions at the national and global level. Sally is a frequent contributor to expert panels convened by groups such as the National Quality Forum, Agency for Health Care Research and Quality, The Commonwealth Fund, Center for Medical Technology Policy, National Patient Advocacy Foundation, the American College of Cardiology's Diabetes Collaborative Registry, the Schwartz Center for Compassionate Care and many others. In 2017 Sally joined the Board of Directors for Public Responsibility in Medicine and Research (PRIM&R). Okun received her nursing diploma from the Hospital of St. Raphael School of Nursing, her baccalaureate degree in nursing science from Southern Connecticut State University, and her

Master's degree from The Heller School for Social Policy & Management at Brandeis University. She was a 2010 Fellow in Biomedical Informatics for the National Library of Medicine and a 2014 Salzburg Global Fellow in New Paradigms for Behavioral and Mental Health.

**P. Pearl O'Rourke, MD**, is the Director of Human Research Affairs at Partners HealthCare Systems in Boston and an Associate Professor of Pediatrics at Harvard Medical School. She is responsible for the systems that support the regulatory and ethical oversight of human research and the responsible conduct of research. She is also Chair of the Partners Healthcare System ESCRO (Embryonic Stem Cell Research Oversight) Committee.

Pearl has worked as a pediatric critical care physician at the Children's Hospital, Boston and at the Children's Hospital, University of Washington, Seattle where she was the Director of the Pediatric Intensive Care Unit. Following a 1995 -1996, Robert Wood Johnson Health Policy fellowship working for Senator Edward Kennedy, she became the Deputy Director of the Office of Science Policy in the Office of the Director at the NIH where she worked on issues such as privacy, gene therapy (transfer) embryonic stem cells, and genetic discrimination.

**Irene Pasquetto, MA**, Center for Knowledge Infrastructures, University of California Los Angeles (UCLA) Department of Information Studies. She is a PhD Candidate in the Information Studies Department at UCLA. In her work, Irene investigates the promises and challenges of open science in bio-medicine, with a focus on data and code sharing practices, and their policy and economic implications.

**Heather H. Pierce, JD, MPH**, senior director for science policy and regulatory counsel in scientific affairs at the Association of American Medical Colleges (AAMC). Ms. Pierce serves as AAMC's leader on issues related to conflicts of interest, human subjects protection, regulatory compliance, and interactions between industry, government, and academia in biomedical research. Prior to joining AAMC, Heather was an attorney in the health care group of the law firm of Ropes & Gray LLP in New York. Her practice focused on regulatory compliance issues including research with human subjects, medical information privacy and security, and fraud and abuse counseling. She worked with a wide range of clients including academic medical centers, hospitals, universities, and pharmaceutical and device manufacturers. She earned her juris doctor at New York University and her master's degree in public health at Boston University. Prior to becoming a lawyer, Heather worked in development and public education for an academic medical center and as a freelance writer. In addition to being PRIM&R's Board Secretary, she also serves as chair of the Governance Committee.

**Suzanne M. Rivera, MSW, PhD**, is the Vice President for Research and Technology Management at Case Western Reserve University in Cleveland, Ohio. She also is a faculty member in the Department of Bioethics at the CWRU School of Medicine and serves as the Institutional Official for Human Research Protections. Her scholarly interests include research ethics, health disparities, and science policy. Dr. Rivera has served on the US Department of Health and Human Services Secretary's Advisory Committee on Human Research Protections (SACHRP) and the Environmental Protection Agency's Human Studies Review Board. Lately, her research focus has been on the ethical and policy implications of biospecimen collection, biobanking, and use of specimens in research. In addition to her numerous published journal articles, Rivera's co-edited book, *Specimen Science*, will be released by MIT press this summer. Dr. Rivera received a Bachelor of Arts degree in American Civilization from Brown University, a Master's degree in social welfare from the University of California-Berkeley, and a doctoral degree in public policy from the University of Texas.



**Laura Lyman Rodriguez, PhD**, is the Director of the Division of Policy, Communications, and Education at the National Human Genome Research Institute (NHGRI). NHGRI is part of the National Institutes of Health (NIH). Her responsibilities include policy development related to NHGRI's research initiatives, communication and outreach activities to engage the public in genomic science, and programs to prepare health care professionals for the integration of genomic medicine into clinical care. Dr. Rodriguez is particularly interested in the policy and ethics questions related to the inclusion of human research participants in genomics and genetics research. In addition, Dr. Rodriguez provided leadership for the development of NIH genomic data sharing policies since their inception in 2007, and continues to contribute to the oversight of their implementation.

Dr. Rodriguez has been with NHGRI since 2002 serving in multiple capacities before being appointed as the DPCE Director. Prior to coming to NIH, Dr. Rodriguez spent time at the National Academies' Institute of Medicine, where she focused on the federal system for protecting human research participants, the Office of Public Affairs at the Federation of American Societies for Experimental Biology, and on Capitol Hill.

Dr. Rodriguez received her bachelor of science with honors in biology from Washington and Lee University in Virginia and earned a doctorate in cell biology from Baylor College of Medicine.

**Stephen Rosenfeld, MD, MBA**, is currently the Executive Chairperson of the Review Board at Quorum Review IRB, an Independent IRB located in Seattle. Dr. Rosenfeld is a hematologist who earned his medical degree from Cornell. He trained in internal medicine at Dartmouth and completed his hematology fellowship at the National Heart, Lung, and Blood Institute of the NIH. He spent 19 years at NIH, holding positions at NHLBI and the NIH Clinical Center, doing both basic and clinical research, and finally working in medical informatics and administration. He ended his time at the NIH as the Chief Information Officer of the Clinical Center. Dr. Rosenfeld moved from Bethesda, Maryland to Portland, Maine, where he was the CIO of MaineHealth, a large independent delivery network, before moving to Olympia, Washington as the CEO of the Western Institutional Review Board. In addition to his medical degree, he holds a Masters in Business Administration from Georgetown. Dr. Rosenfeld received the honor of Distinguished Professor of Medicine from Daegu Catholic University Medical Center in Korea in 2013. In July 2013, he was appointed to the Secretary's Advisory Committee on Human Research Protections (SACHRP) and in 2016 he was appointed Chair of SACHRP.

**Joseph S. Ross, MD, MHS**, is an Associate Professor of Medicine (General Medicine) and of Public Health (Health Policy and Management) at the Yale University School of Medicine, a member of the Center for Outcomes Research and Evaluation at the Yale-New Haven Hospital, and an Assistant Director of the Robert Wood Johnson Foundation's Clinical Scholars program at Yale. His expertise includes performance measure development and understanding the translation of clinical research into practice, using health policy research methods to examine the use and delivery of higher quality care and to better understand issues related to pharmaceutical and medical device regulation, evidence development, postmarket surveillance, and clinical adoption. Dr. Ross has published more than 200 articles in peer-reviewed biomedical journals and is currently an Associate Editor at *JAMA Internal Medicine*.

**Alan Rubel, JD, PhD**, is an associate professor in the iSchool and the Center for Law, Justice, and Society at the University of Wisconsin, Madison. He works in the areas of information ethics and policy, and has recently published articles on student privacy in data analytics systems, health information privacy (in pragmatic clinical trials, in public health surveillance), and in licensing agreements for electronic resources in libraries. In 2012 he served as Senior Advisor to the

Presidential Commission for the Study of Bioethical Issues. Prior to joining the faculty at UW, he was a Greenwall Fellow in Bioethics at Johns Hopkins and Georgetown universities and law clerk to Justice Ann Walsh Bradley on the Wisconsin Supreme Court.

**Ada Sue Selwitz, MA**, is responsible for assisting the University of Kentucky in developing institutional policies pertaining to a variety of compliance issues such as protection of human subjects, scientific misconduct, and data retention. Since 1979, she has worked at the University of Kentucky in a variety of roles including director of sponsored program development, director of the Office of Research Integrity, and executive integrity/compliance advisor. She has an adjunct associate professor appointment in the Department of Behavioral Sciences in the College of Medicine. Ms. Selwitz has co-authored publications and given over 150 presentations. Ms. Selwitz has been involved in research projects funded by the National Institutes of Health. She has been the recipient of several national awards such as Society of Research Administrators Excellence Award, Applied Research Ethics National Association Distinguished Service Award, ARENA Appreciation Award, and National Council of University Administrators Outstanding Achievement in Research Administration Award. She served on the Department of Health and Human Services (DHHS) Advisory group on the Public Health Service Responsible Conduct of Research policy, the NIH Regulatory Burden Committee, the DHHS Secretary Advisory Committee on Human Research Protection, and the CITI Advisory Board. She served on the PRIM&R Board from 1987-2016.

**Sharon Shriver, PhD**, Director of Programs for Public Responsibility in Medicine and Research, where she helps lead the organization in its efforts to educate and engage the public and the research community on research ethics and public policy issues. Prior to joining PRIM&R, Dr. Shriver was Assistant Director of Penn State's Office for Research Protections, where she led the university's research integrity educational initiatives. The Scholarship and Research Integrity at PSU (SARI@PSU) program, which she helped create, has reached over 10,000 students and researchers with discipline-specific, interactive programs on the responsible conduct of research. Dr. Shriver has been a member of the Developer's Group of the Collaborative Institutional Training Initiative at the University of Miami, serving with the Responsible Conduct of Research working group. Dr. Shriver has extensive background in science and ethics, having taught undergraduate and graduate courses in genetics, molecular medicine, and bioethics at Penn State and the University of Pittsburgh. Her doctoral work in molecular genetics led to her early career as a clinical investigator at the MD Anderson Cancer Center and the University of Pittsburgh Medical Center, identifying smoking-induced mutations that contribute to the increased risk of women for lung cancer.

**David H. Strauss, MD**, is a psychiatrist and Director of Research Operations and Compliance, New York State Psychiatric Institute and the Columbia University Department of Psychiatry where he oversees human and animal research affairs, research integrity, conflict of interest and core research functions. From 2000 until 2010, Dr. Strauss chaired the NYSPI IRB and directed the Office of Human Subjects Research. He currently co-chairs Columbia University's Standing Committee on the Conduct of Research. Dr. Strauss is past recipient of two NIH grants on research ethics training and the enhancement of human subjects oversight for psychiatric research. He is a former member of SACHRP and completed work as co-chair of its Subcommittee on the Inclusion of Individuals with Impaired Decision-making in Research. He currently serves on a SACHRP subcommittee charged with developing recommendations to enhance Subpart A or the "Common Rule." Dr. Strauss practices psychiatry and psychopharmacology, and teaches, lectures, and consults widely on matters of human subjects protections and applied research ethics. He serves on PRIM&R's Board of Directors and is Chair of the Public Policy Committee.

**Jeremy Sugarman, MD, MPH, MA**, is the Harvey M. Meyerhoff Professor of Bioethics and Medicine, Professor of Medicine, Professor of Health Policy and Management, and Deputy Director for Medicine of the Berman Institute of Bioethics at the Johns Hopkins University. He is an internationally recognized leader in biomedical ethics with particular expertise in applying empirical methods and evidence-based standards for evaluating and analyzing bioethical issues. His contributions to both medical ethics and policy include his work on the ethics of informed consent, umbilical cord blood banking, stem cell research, international HIV prevention research, global health and research oversight.

He served as senior policy and research analyst for the White House Advisory Committee on Human Radiation Experiments, consultant to the National Bioethics Advisory Commission, and Senior Advisor to the Presidential Commission for the Study of Bioethical Issues. He was a member of the Board of Directors of PRIM&R (Public Responsibility in Medicine and Research) from 2011-2016. He is a member of PRIM&R's Public Policy Committee.

Dr. Sugarman has been elected as a member of the American Society of Clinical Investigation, Association of American Physicians, and the Institute of Medicine. He is a fellow of the American Association for the Advancement of Science, the American College of Physicians and the Hastings Center.

**John Wilbanks**, is the Chief Commons Officer at Sage Bionetworks. Previously, Wilbanks worked as a legislative aide to Congressman Fortney "Pete" Stark, served as the first assistant director at Harvard's Berkman Center for Internet & Society, founded and led to acquisition the bioinformatics company Incellico, Inc., and was executive director of the Science Commons project at Creative Commons. In February 2013, in response to a We the People petition that was spearheaded by Wilbanks and signed by 65,000 people, the U.S. government announced a plan to open up taxpayer-funded research data and make it available for free. Wilbanks holds a B.A. in philosophy from Tulane University and also studied modern letters at the Sorbonne.

**Alexandra Wood, JD, MPP**, is a fellow at the Berkman Klein Center for Internet & Society at Harvard University and a researcher contributing to the Center's privacy initiatives. In this role, she is a collaborator with the Harvard Privacy Tools for Sharing Research Data project, providing legal and policy expertise as part of a broad, multidisciplinary effort to build new tools for responsible data sharing. Her research involves exploring legal and regulatory frameworks for privacy and data protection, in light of recent advances in privacy from fields such as computer science, social science, and law. She also contributes to the development of new frameworks for assessing privacy risks and formalizing aspects of privacy regulation for the design of combined legal and technical tools for analyzing and sharing privacy-sensitive data. Previously, Alexandra served as a legal fellow assisting with the technology, telecommunications, and intellectual property portfolio of U.S. Senator Barbara Boxer. As a law student, she worked with the Center for Democracy & Technology and the Electronic Privacy Information Center. She was also a 2010 Google Policy Fellow with the Future of Music Coalition.

**Michael Zimmer, PhD**, is an Associate Professor in the School of Information Studies at the University of Wisconsin-Milwaukee, where he also serves as Director of the Center for Information Policy Research. Dr. Zimmer is a privacy and internet ethics scholar, most notable for his work in online privacy, the ethical dimensions of social media & internet technologies, libraries & privacy, and internet research ethics.