Breakout Session on " Streamlining Access to Controlled Data at NIH: Tackling Challenges and Identifying Opportunities”

July 26, 12:30 to 2:00 p.m.

Panelist Biographies

Michael Feolo, M.S.
Staff Scientist, dbGaP Team Lead, National Center for Biotechnology Information
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Michael Feolo is a staff scientist at the NIH’s National Center for Biotechnology Information, and since 2007 has been the team lead for the NCBI’s database of Genotypes and Phenotypes (dbGaP). The dbGaP is a database designed to allow researchers public access to questionnaires, protocols, methods, phenotypes, molecular data and the results of association analyses in whole genome case/control and longitudinal studies of heritable disease. Through his work on dbGaP and service on several trans-NIH data sharing and policy committees, Michael received the NLM’s Rodger’s Award in 2011, and NIH Director’s awards in 2013 and 2014. Prior to leading the dbGaP team, 2000-2007, Michael worked on developing dbSNP, NCBI’s database of genetic variation and dbMHC, NCBI’s database focused on the variations in the HLA genes located in a region on human chromosome 6 known as the Major Histocompatibility Complex (MHC). During this time, Michael participated as a member of the International HapMap planning and analysis committees and coordinated the upload of genotype data from HapMap to the dbSNP. Michael received a BS in Molecular Biology, from the University of Utah 1996, was awarded and National Library of Medicine fellowship in 1997, and earned a MS in Medical Informatics, from the University of Utah, Department of Biomedical Informatics in 1999.

Rebecca F. Rosen, PhD
Director, Office of Data Science and Sharing, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health
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Subject Matter Expertise: Dr. Rosen led the streamlining of the end-to-end data access governance workflow at the NIMH Data Archive, including updates to the data permissions model, the Data Use Certification, and the data access request and review software.
Dr. Rosen is working to catalyze responsible use of data and biospecimens generated by the NICHD community. She is also the Product Owner for the NIH Researcher Auth Service (RAS), an NIH resource for centralized and secure identity and access management across the NIH research data ecosystem. Previously she was a Senior Advisor in the Office of Technology Development and Coordination in the National Institute of Mental (NIMH) and the Program Lead for the NIMH Data Archive (NDA). NDA is NIMH's single data repository for human subjects data and securely makes available for secondary analysis clinical, phenotypic, imaging, and omics data from over 500,000 subjects across over 1,300 research projects.   Previously, Dr. Rosen was a Research Assistant Professor at New York University's Institute for the Study of Decision Making and Chief Data Officer for the HUMAN Project. She was Associate Director for Data Resources and Data Strategy at the Center for Urban Science and Progress (CUSP) at NYU. Prior to NYU, Dr. Rosen co-founded the Center for the Science of Science & Innovation Policy at the American Institutes for Research, working with US and international science funders to build data platforms for research management. She has been a policy analyst at both the National Science Foundation and the National Institutes of Health. Dr. Rosen earned a PhD in neuroscience from Emory University and a BS in psychobiology from Yale University.

Christopher J. Lindsell, PhD
Professor of Biostatistics and Biomedical Informatics, Vanderbilt University Medical Center
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Subject Matter Expertise: Dr. Lindsell leads data coordinating centers for clinical trials and epidemiological studies, each with data sharing and reuse requirements. In addition, recent responsibilities include supporting the data standards efforts of CONNECTS, NHLBI's network of networks for COVID-19 research, and the development of a federated machine learning network for EMPACT, an emerging precision trials network.

Dr. Lindsell is director of the Vanderbilt Institute for Clinical and Translational Research Methods program, co-Director of the Center for Health Data Science, and professor of biostatistics at Vanderbilt University Medical Center. His research portfolio is focused on health systems and services, biomarker discovery and validation, and clinical trials in acute care environments. He has published over 300 peer-reviewed papers and has led the data coordinating center for numerous multi-center clinical trials and epidemiologic studies including ACTIV6 and the IVY Network. He has contributed to data standards for CONNECTS, NHLBI's network of networks for COVID-19 research, and to the DAQCORD guidelines for data collection and curation in observational studies. He is co-lead of Vanderbilt University Medical Center's Learning Health System where he applies his expertise in the design and execution of pragmatic effectiveness trials, as well as in risk stratification and predictive modeling. He holds patents for using clinical information, biomarkers and transcriptomics for prognosis and prediction in sepsis and septic shock and is currently leading efforts to develop a precision clinical trial network and a federated AI network to improve the care of critically ill patients.

Ana Navas-Acien, MD, PhD
Professor and Vice Chair of Research and Faculty Affairs, Department of Environmental Health Sciences, Columbia University Mailman School of Public Health
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Dr. Navas-Acien is a physician-epidemiologist (MD, University of Granada, Spain '96) with a specialty in Preventive Medicine and Public Health (Hospital La Paz, Madrid '01) and a PhD in Epidemiology (Johns Hopkins University '05). Her research investigates the long-term health effects of environmental exposures (arsenic and other metals, tobacco smoke, e-cigarettes, air pollution), their interactions with genetic and epigenetic variants, and effective interventions for reducing involuntary exposures. She collaborates with major cohort studies such as the Strong Heart Study, a study of cardiovascular disease and its risk factors in American Indian communities, and the Multi-Ethnic Study of Atherosclerosis (MESA), a study of cardiovascular, metabolic and lung disease in urban settings across the US. Both in the US and internationally, she evaluates exposure to tobacco smoke including emerging public health challenges such as waterpipe smoking and e-cigarettes. Her goals are to contribute to the reduction of environmental health disparities in underserved and disproportionately exposed populations.

Sarion Bowers, PhD
Head of Policy, Wellcome Sanger Institute
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Subject Matter Expertise: Sarion Bowers is the Head of Policy at the Wellcome Sanger Institute. She works primarily on UK science policy, with a particular focus on genomics and genomic technologies. She has a particular interest in data protection and the ethical, legal and societal issues that arise from the use of genomics, including genome editing.

Dr. Bower's role is to work with national and international policy makers and science advocates to develop good governance and legislation and to ensure the Institute has policies in place that make our research legally compliant and of the highest ethical standards. The research at the Sanger Institute touches on a very wide range of ethical and legal issues, and topics such as use of human tissue and sharing of genomic data can be very sensitive. It is therefore critically important that our research respects the expectations and privacy those individuals who volunteer to participate in our research. Dr. Bowers is currently working on a number of projects including: Looking at how to improve the quality of the data we share and how researchers can better identify useful datasets, The ethical, legal and policy issues around use of human tissue in large-scale resources for the science community, The ethics and governance of genome editing, Good research practice and academic conduct, All-Party Parliamentary Group on innovative health. Dr. Bowers works with people across the Institute, including the faculty, public engagement and the Director's Office, as well as with the Wellcome Trust and other science advocacy groups in order to engage policy makers in the UK and in Europe and to bring the Institute's voice to the various debates around the world on bioethics and the use of genomics and data in healthcare. She is also responsible for the research policies of the Institute to ensure that our research is not only legal but employs the highest ethical standards.

Bradley Malin, Ph.D.
Vice Chair of the Department of Biomedical Informatics at Vanderbilt University Medical Center and the Accenture Professor of Biomedical Informatics, Biostatistics, and Computer Science at Vanderbilt University, Co-director of the Vanderbilt Health Data Science (HEADS) Center and the Center for Genetic Privacy and Identity in Community Settings (GetPreCiSe), an NIH Center of Excellence in Ethical, Legal, and Social Implications Research.
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Dr. Malin builds technologies that enable privacy and analytics in the context of real world organizational, political, and health information architectures. To ensure practical solutions, his work draws upon methodologies in computer science, biomedical science, and public policy to innovate novel computational techniques. In addition to running a scientific research program, since 2007, he has led a data privacy service for the Electronic Medical Records and Genomics (eMERGE) network, an NIH consortium, and currently serves as the co-chair of the Committee on Access, Privacy, and Security of the NIH-sponsored All of Us Research Program. He is an appointed member of the Technical Anonymisation Group of the European Medicines Agency and a member of the Board of Scientific Counselors of the National Center for Health Statistics of the U.S. Centers for Disease Control and Prevention. He is an elected fellow of the National Academy of Medicine (NAM), the American College of Medical Informatics (ACMI), the International Academy of Health Sciences Informatics (IAHSI), and the American Institute for Medical and Biological Engineering (AIMBE).

Tiffany Boughtwood, BSc, MBA
Managing Director, Australian Genomics
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Subject Matter Expertise: I have managed the genomic research programs amounting to $100M in Australian government research investment, including Australian Genomics (2016-2020; 2021-2023) and Mackenzie's Mission (2019-2022). In this capacity, I have contributed to the development of data policies and practices for these cohorts.

Tiffany Boughtwood is the Managing Director of Australian Genomics, an Australian Government initiative supporting genomic research and its translation into clinical practice through broad engagement and a collaborative national approach.
Tiffany has 25 years' experience in molecular biology and research management: leading academic and diagnostic laboratories; collaborating internationally in genetic and genomic research; and consulting in genomic implementation and management. She has served on the World Economic Forum Global Future Council for Biotechnology, the WHO Collective Global Network for Rare Disease, and is a founding Director of the Childhood Dementia Initiative.

Warren A. Kibbe, PhD, FACMI
Professor in Biostatistics and Bioinformatics, chief for Translational Biomedical Informatics in the Department of Biostatistics and Bioinformatics and Chief Data Officer for the Duke Cancer Institute
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Dr. Kibbe is Vice Chair and Professor of Biostatistics and Bioinformatics at Duke University. His research interests include data representation for clinical trials, especially improving the computability and interpretability of biomarker and eligibility criteria and data interoperability between medical records and decision support algorithms. Dr. Kibbe has been a proponent for open science and open data in biomedical research and helped define the data sharing policy for the NCI Cancer Moonshot program. Prior to joining Duke, he served as an acting deputy director of the NCI and was the director of the NCI's Center for Biomedical Informatics and Information. He was one of the architects of the NCI Genomic Data Commons initiative. Dr. Kibbe is a co-founder of the Cancer Informatics for Cancer Centers (Ci4CC.org) society. Dr. Kibbe is an MPI on the NIH/NIMHD-funded RADx-Underserved Populations Coordination and Data Collection Center and an MPI in the NIH/NHGRI-funded Duke Center for Combinatorial Gene Regulation.

Julia Slutsman, PhD
Director, Genomic Data Sharing Policy Implementation Office of Extramural Research NIH
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Dr. Julia Slutsman is a bioethicist and Director of the Genomic Data Sharing Policy Implementation Office in the Office of Extramural Research, NIH. Her work focusses on supporting coordination of activities necessary for effective implementation of NIH data sharing policies while maintaining research participant confidentiality and data privacy. Previously, Dr. Slutsman worked as the Director of Research Regulatory Affairs at Children's National Medical Center and was an Assistant Professor of Pediatrics at the George Washington University School of Medicine and Health Sciences. She has extensive expertise in implementing human subject protections, clinical research compliance and in developing policy for research oversight of pediatric and adult clinical research programs. Dr. Slutsman has held numerous positions within the National Institutes of Health. She worked as a bioethicist in the NIH Office of Human Subject Protections and in the Department of Bioethics. She served as the bioethicist for the National Children's Study at the Eunice K. Shriver Institute of Child Health and Human Development. She has conducted and published empirical bioethics research in a number of areas. Her current research interests include informed consent and data sharing in research, ethical and policy implications of single IRB review of research, parental decision-making in research involving children and ethical issues related to the review and conduct of public health emergency research. Dr. Slutsman earned her Ph.D. from the Program in Law, Ethics and Health at the Johns Hopkins University Bloomberg School of Public Health. She completed a post-doctoral fellowship in the ethics of public health and cancer prevention at the National Cancer Institute.

Jonathan Lawson, PMP, CSPO
Senior Software Product Manager, Broad Institute of MIT and Harvard
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Subject Matter Expertise: data access request processes, data access agreements, standardized data sharing language, computer-assisted decision-making

Jonathan leads DUOS (Data Use Oversight System) Broad's data access and sharing software platform, co-leads the GA4GH DURI workstream's Data Use group, Data Use Ontology (DUO) standard, Data Access Committee Review Standards (DACReS), and Machine Readable Consent Guidance (MRCG) standard, is a member of the NHGRI AnVIL Data Access Working Group, and is Vice Chair of Broad's Data Access Committee

Alexander Ropelewski
Director, Biomedical Applications Group Pittsburgh Supercomputing Center

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Subject Matter Expertise: High Performance Computing and Data

Alexander Ropelewski cultivated his 30+ year professional career at the Pittsburgh Supercomputing Center where he directs the Biomedical Applications Group, a group focused on enhancing the use of High-Performance Computing, Networking, and Data Science within the Biomedical Research Community. A computer scientist graduate from the University of Pittsburgh, Ropelewski's HPC work includes the creation of parallel codes on a wide-range of computing architectures and major contributions to architectural frameworks for data-intensive projects. Ropelewski is currently PI and Operations Director for the Brain Image Library (BIL), an NIH funded national public resource enabling researchers to deposit, analyze, mine, share and interact with large brain image datasets. Other data intensive projects Ropelewski currently contributes to include the AUROA-US Breast Cancer Data Coordinating Center and the Infrastructure and Engagement component of the National Institutes of Health HuBMAP project. In addition to those data intensive projects, Ropelewski co-directs the training and dissemination components of the National Center for Multiscale Modeling of Biological Systems. In the recent past, he led the PSC's NIH funded MARC program, a multi-institutional collaborative bioinformatics training effort involving scientists and educators at several Minority Serving Institutions.