2019 OHRP EXPLORATORY WORKSHOP

Privacy & Health Research in a Data-Driven World

THURSDAY, SEPTEMBER 19, 2019

OHRP
Office for Human
Research Protections

PROGRAM BOOK

INTRODUCTION

BACKGROUND

The rapidly changing landscape of biomedical and health-related behavioral research continues to present diverse challenges for adequately reviewing and appropriately regulating research to best protect human research subjects. Charged with the mission of providing leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS), the Office for Human Research Protections (OHRP) endeavors to keep abreast of these challenges with the long-term goal of developing meaningful policy guidance that responds to them.

OHRP's Division of Education and Development (DED) promotes education and outreach on the protection of human subjects in research. DED created the OHRP Exploratory Workshop to provide a platform for collegial intellectual exchanges within the research community to promote exploration of a topic of interest that hinges on the Federal regulations or human subjects protection. This OHRP Exploratory Workshop explores the ethical and regulatory dimensions of big data use in health research.

OBJECTIVES

The purpose of OHRP's Exploratory Workshop is to provide a platform for open dialogue and exchange of ideas between stakeholders in the regulated community. The objectives for this workshop on privacy and big data health research include:

- Discuss the ethical concerns and other considerations prompted by big data health research

- Share evidence-based practices for facilitating data sharing while maintaining necessary privacy protections

- Provide a forum for the research community to identify challenges encountered when assessing and evaluating proposed privacy protections for big data research, and to share ideas for responding to these challenges

- Spark interest in research and practical applications of scholarship that could inform future practices to protect research participants

AGENDA

Time	Sessions
8:15 AM – 8:25 AM	**Welcome and Introduction (OHRP)**
8:25 AM – 10:30 AM	**Session I: Is Privacy a Casualty of Advancing Research?** **Moderator:** Jodi Daniel, J.D., M.P.H.; *Crowell & Moring LLP* The goal of this session is to explore the problem of privacy protection in a data-rich world, the tensions that exist between the societal good that could come from big data research and the real and perceived risks to individuals, as well as the public's perspectives about broad data sharing. Panelists will discuss the ethical considerations related to large-scale open data sharing including questions about data ownership, the types and goals of big data research that might be pursued, what needs to be done to maintain public trust in health research, and who are the responsible parties.
8:25 AM	**Session I Introduction** Jodi Daniel, J.D., M.P.H.; *Crowell & Moring LLP*
8:30 AM	**Reconsidering Research Ethics in Big Data Research** Jacob Metcalf, Ph.D.; *Data & Society Research Institute*
8:50 AM	**Striking a Balance: Benefit-Risk Analysis for Big Data Research** Brenda Leong; *Future of Privacy Forum*
9:10 AM	**Public Perspectives on Data Sharing and Privacy** Cinnamon Bloss, Ph.D.; *University of California, San Diego*
9:30 AM	**Panel Discussion for Session I**
10:30 AM – 10:55 AM	**Break**
10:55 AM – 1:00 PM	**Session II: Approaches to Protecting Privacy & Confidentiality** **Moderator:** Mark Barnes, J.D., LL.M.; *Ropes & Gray, LLP* Speakers representing diverse stakeholders in the research enterprise will discuss policies, techniques, and technologies for controlled use, data protection, and informed consent as ways to protect individual privacy and data confidentiality. The goal of this session is to explore the challenges of privacy protection for health-related big data research conducted on a variety of platforms and in various settings. Panelists will also consider the ethical and practical challenges posed by data-sharing across cultures and boundaries.
10:55 AM	**Session II Introduction** Mark Barnes, J.D., LL.M.; *Ropes & Gray, LLP*
11:00 AM	**Transforming Health Measurement and Care Delivery Through Patient-Generated, Permissioned Data from Daily Life** Deborah Kilpatrick, Ph.D.; *Evidation Health*

AGENDA

Time	Sessions
11:15 AM	**CMS Data Products** Andrew Shatto; *Centers for Medicare and Medicaid Services (CMS)*
11:30 AM	**The Vivli Experience in Sharing Clinical Trial Data Globally** Rebecca Li, Ph.D.; *Vivli*
11:45 AM	**The Use of 'Differential Privacy' as a Statistical Method for Protecting Confidentiality in Data Publications** Simson L. Garfinkel, Ph.D.; *US Census Bureau*
12:00 PM	**Panel Discussion for Session II**
1:00 PM – 2:00 PM	**Lunch Break (60 minutes)**
2:00 PM – 4:10 PM	**Session III: Protecting Privacy & Confidentiality: A Shared Responsibility** **Moderator:** Elizabeth Buchanan, Ph.D.; *University of Wisconsin-Stout* The goals of this session are to discuss some of the challenges facing IRBs and institutions in the review of proposed data sharing options for research that falls under the Common Rule, and explore ethical oversight of big data research that falls outside the scope of the Common Rule. Invitees will explore the possible roles of a variety of stakeholders for supporting responsible conduct of research involving big data in addition to potential approaches to ethical evaluation of proposed big data research.
2:00 PM	**Session III Introduction** Elizabeth Buchanan, Ph.D.; *University of Wisconsin-Stout*
2:05 PM	**IRBs and Big Data Research** Michael Zimmer, Ph.D.; *Marquette University (as of August 1)*
2:20 PM	**A Framework for Ethics Committees for Reviewing Research Protocols with Privacy and Confidentiality-Related Risks in Electronic Environment** Adarsh K. Gupta, D.O., M.S., FACOFP; *Rowan School of Medicine*
2:35 PM	**Facing the Future: Operational Solutions to the Regulatory Challenges of Big Data Research** Megan Kasimatis-Singleton, J.D., M.B.E., CIP; *Johns Hopkins University School of Medicine*
2:50 PM	**Ethical Considerations for the Review of Big Data Research Beyond the Common Rule** Brenda Leong; *Future of Privacy Forum*
3:00 pm	**Shared Responsibility in Ethical Big Data Research** Jacob Metcalf, Ph.D.; *Data & Society Research Institute*
3:10 pm	**Panel Discussion for Session III**
4:10 pm – 4:15 pm	**Closing**

The goal of this session is to explore the problem of privacy protection in a data-rich world, the tensions that exist between the societal good that could come from big data research and the real and perceived risks to individuals, as well as the public's perspectives about broad data sharing. Invitees will discuss the ethical considerations related to large-scale open data sharing including questions about data ownership, the types and goals of big data research that might be pursued, what needs to be done to maintain public trust in health research, and who are the people responsible.

Session I Introduction

Jodi Daniel, *J.D., M.P.H. (Moderator)*
Crowell & Moring LLP

Jodi Daniel is a partner in Crowell & Moring's Health Care Group and a director at C&M International (CMI), an international policy and regulatory affairs consulting firm affiliated with Crowell & Moring. She leads the firm's Digital Health Practice and provides strategic, legal, and policy advice to all types of health care and technology clients navigating the dynamic regulatory environment related to technology in the health care sector to help them achieve their business goals. Prior to joining Crowell & Moring, Jodi was the founding director of the Office of Policy in the Office of the National Coordinator for Health Information Technology (ONC), U.S. Department of Health and Human Services (HHS) for a decade after serving in the Office of the General Counsel (OGC) at HHS for five years. At HHS, Jodi helped spearhead important changes in health information privacy and health information technology to improve health care for consumers nationwide. She was also one of the key drafters of the original Health Insurance Portability and Accountability Act (HIPAA) Privacy Rules and Enforcement Rules and developed the Nationwide Privacy and Security Framework for Electronic Exchange of Health Information.

As the first senior counsel for health information technology at HHS, Jodi developed the foundational legal strategies and coordinated all legal advice regarding health IT for HHS, founded and chaired the health information technology practice group within OGC, and worked closely with CMS in the development of the e-prescribing regulations and the Stark and anti-kickback rules regarding e-prescribing and electronic health records. Jodi began her career at a large insurance company advising employers on managed care and group health benefits.

Reconsidering Research Ethics in Big Data Research

Jacob Metcalf, Ph.D.
Data & Society Research Institute

Jacob (Jake) Metcalf, Ph.D. is a technology ethics researcher and consultant specializing in data analytics and artificial intelligence. He is a Researcher at Data & Society on an NSF-funded multisite project, Pervasive Data Ethics for Computational Research (PERVADE). For this project, he studies how data ethics practices are emerging in environments that have not previously grappled with research ethics, such as industry, conference committees, and civil society organizations. He also studies how design practices can successfully integrate ethical values and principles. Jake also runs a consulting firm, Ethical Resolve, LLC, that provides clients with a range of ethics services, helping clients make well-informed, consistent, actionable and timely business decisions that reflect their values. He lives amongst the redwoods of the Santa Cruz mountains.

Striking a Balance: Benefit-Risk Analysis for Big Data Research

Brenda Leong
Future of Privacy Forum

Brenda Leong, CIPP/US, is Senior Counsel and Director of Strategy at the Future of Privacy Forum. She oversees strategic planning of organizational goals, as well as managing the FPF portfolio on biometrics, particularly facial recognition, along with the ethics and privacy issues associated with artificial intelligence. She works on industry standards and collaboration on privacy concerns, by partnering with stakeholders and advocates to reach practical solutions to the privacy challenges for consumer and commercial data uses. Prior to working at FPF, Brenda served in the U.S. Air Force, including policy and legislative affairs work from the Pentagon and the U.S. Department of State. She is a 2014 graduate of George Mason University School of Law.

Public Perspectives on Data Sharing and Privacy

Cinnamon Bloss, Ph.D.
University of California, San Diego

Dr. Cinnamon Bloss is an Associate Professor in the Departments of Psychiatry (primary) and Family Medicine and Public Health (secondary), Division of Health Policy at the University of California, San Diego. Dr. Bloss has an adjunct appointment as a Policy Analyst at the J. Craig Venter Institute and is a licensed clinical psychologist. Dr. Bloss' current research focuses on the individual and societal impacts of emerging biomedical technologies. Dr. Bloss' background is in clinical psychology, statistical genetics, genomic medicine, biomedical ethics, and health policy. Dr. Bloss has been Principal Investigator or Co-Investigator on several National Institutes of Health and other grants and has published over 70 papers and mentored over 30 students.

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Session II Introduction

Mark Barnes, J.D., LL.M. *(Moderator)*
Ropes & Gray, LLP

Since 2014, Mark has taught health care law and public health law at Yale University Law School, and since 1999, he has taught the history of the regulation of the medical profession and other legal-medical issues in the first year curriculum of Yale University Medical School. Mark is a partner at the international law firm, Ropes & Gray, where his client work focuses on human and animal research, stem cell and genetic research, research fraud, and international research. Mark formerly served at Harvard as the Senior Associate Provost for Research, and in 2004 started and directed for several years Harvard's HIV/AIDS treatment programs in Nigeria, Tanzania, and Botswana. He has served as chief administrative officer at St. Jude Children's Research Hospital, and has held senior appointed positions in the New York City and State departments of health. Mark is co-chair of the Subcommittee on Harmonization of Research Regulations, HHS Secretary's Advisory Committee on Human Subjects Protections, and is a member of the Ethics Working Group of the NIH HIV Prevention Clinical Trials Network. He serves as the faculty Co-Chair of the Multi-Regional Clinical Trials Center of Harvard and Brigham and Women's Hospital, which works with researchers, industry and regulators to improve standards and regulations for clinical trials, with a focus on the emerging economies.

Public Perspectives on Data Sharing and Privacy

Deborah Kilpatrick, Ph.D.
Evidation Health

Deborah Kilpatrick, Ph.D. is the CEO of the digital health company Evidation Health in California. Evidation is a new kind of health and measurement company that provides the world's most innovative healthcare companies technology and expertise to understand how everyday behavior and health interact. Earlier in her career, she held multiple leadership roles in R&D, new technology development, and New Ventures at Guidant Corporation prior to its acquisition by Boston Scientific (NYSE: BSX), followed by commercial roles at genomic medicine company CardioDx. She currently sits on the college of engineering advisory boards for the Georgia Institute of Technology and the California Polytechnic State University. Deborah is a Director for Sleep Number (NASDAQ: SNBR), a fellow of the American Institute of Medical and Biological Engineering, and the co-founder of the MedtechVision Conference now held annually in Silicon Valley. She has has been named to FierceMedicalDevice's Top Women in Medtech, FierceBiotech's Top Women in Biotech, and Silicon Valley Business Journal's 100 Women of Influence. She holds B.S., M.S. and Ph.D. degrees in engineering from Georgia Tech University.

CMS Data Products

Andrew Shatto
Centers for Medicare and Medicaid Services (CMS)

Andrew Shatto is the Deputy Director of the Office of Enterprise Data and Analytics (OEDA) at CMS. Andy's office manages the Chronic Conditions Data Warehouse (CCW) which includes the Research Data Distribution Center (RDDC) and the CMS Virtual Research Data Center (VRDC), the Qualified Entity (QE) Program, the CMS Privacy Board as well as the CMS Data Use Agreement process, and the Research Data Assistance Center (ResDAC). In addition, OEDA develops and maintains a variety of data products designed to provide CMS data to researchers in a linked, secure, and "cleaned up" way allowing analysis on Medicare and Medicaid beneficiaries to be completed across a broad continuum of care. Mr. Shatto has been working at CMS in various programming and data analysis capacities since 1997.

The Vivli Experience in Sharing Clinical Trial Data Globally

Rebecca Li, Ph.D.
Vivli

Rebecca Li, Ph.D., is the Executive Director of Vivli and on faculty at the Center for Bioethics at the Harvard University Medical School. Previous to her current role, she was the Executive Director of the MRCT Center of Brigham and Women's Hospital and Harvard for over five years and remains a Senior Advisor at the Center. She has over 25 years of experience spanning the entire drug development process with expertise in Biotech, Pharma and CRO environments. She completed a fellowship in 2013 in the Division of Medical Ethics at Harvard University Medical School. She earned her Ph.D. in Chemical and Biomolecular Engineering from Johns Hopkins University.

The Use of "Differential Privacy" as a Statistical Method for Protecting Confidentiality in Data Publications

Simson L. Garfinkel, Ph.D.
US Census Bureau

Simson Garfinkel is the Senior Computer Scientist for Confidentiality and Data Access at the US Census Bureau. He holds seven US patents and has published more than 50 research articles in computer security and digital forensics. He is a fellow of the Association for Computing Machinery (ACM) and the Institute of Electrical and Electronics Engineers (IEEE), and a member of the National Association of Science Writers. His most recent book is *The Computer Book*, which features 250 chronologically arranged milestones in the history of computing. As a journalist, he has written about science, technology, and technology policy in the popular press since 1983, and has won several national journalism awards.

Garfinkel received three Bachelor of Science degrees from Massachusetts Institute of Technology (MIT) in 1987, a Master's of Science in Journalism from Columbia University in 1988, and a Ph.D. in Computer Science from MIT in 2005.

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Session III Introduction

Elizabeth Buchanan, Ph.D. *(Moderator)*
University of Wisconsin-Stout

Elizabeth A. Buchanan, Ph.D. is an Endowed Chair in Ethics and Acting Director, Office of Research and Sponsored Programs at the University of Wisconsin-Stout. Her research is focused on the intersections of emerging technologies, ethics, and IRB review. Her latest publications include a commentary on big data in PLOS ONE, a chapter on Internet research methods in the Sage Handbook of Qualitative Research Methods, and an update to Internet Research Ethics in the Stanford Encyclopedia of Philosophy.

Elizabeth is active in Public Responsibility in Medicine and Research (PRIM&R), serving on the faculty roster since 2008 and serving on the Conference Planning Committee since 2012. She was the Conference Co-Chair of PRIM&R's SBER 2015 and 2017 conference, and as of 2016, joined the Board of Directors. Also, Elizabeth served as a member of the American Association for the Advancement of Science Committee on Scientific Freedom and Responsibility between 2012-2017.

In addition to her work on Internet research, Elizabeth is currently the Principal Investigator on her fourth National Science Foundation grant. In her recent study, she is looking at the ethical implications of service learning programs, and specifically, Engineers without Borders.

Elizabeth is the editor of one of the first anthologies of Internet research ethics (Readings in Virtual Research Ethics, 2004), and is author and/or co-author to numerous papers on research ethics and methods. Elizabeth is also primary co-author to the Association of Internet Researchers Ethics Guidelines for Internet Research. She holds Bachelor of Arts degrees from Rutgers University, and her Master's and Ph.D. from the University of Wisconsin-Milwaukee.

IRBs and Big Data Research

Michael Zimmer, Ph.D.
Marquette University (as of August 1)

Michael Zimmer, Ph.D., is a privacy and internet ethics scholar, whose work focuses on digital privacy, internet research ethics, and the ethical dimensions of social, mobile & internet technologies. He currently 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. In Fall 2019, Zimmer will join the Department of Computer Science at Marquette University, where he will continue his focus on data ethics and privacy.

Dr. Zimmer has published in numerous international academic journals and books, and has delivered talks across North America, Europe, and Asia. He has written for Wired, The Washington Post, and The Huffington Post, and has been a guest on National Public Radio's All Things Considered, Morning Edition, Science Friday, and Here & Now news programs. Zimmer has appeared in news articles for The New York Times, The Wall Street Journal, the Associated Press, The Atlantic, The Chronicle of Higher Education, MSNBC. com, CNN.com, GQ Magazine, and various other national and local media outlets. His research has been supported by the National Science Foundation, the Institute of Museum and Library Services, and the American Library Association.

Zimmer has been invited to share his expertise for numerous academic and professional groups, including the National Academies of Sciences, Engineering and Medicine's Committee on Science, Technology, and Law, the Secretary's Advisory Committee on Human Research Protections (SACHRP), PRIM&R (Public Responsibility in Medicine and Research), and he regularly participates in advocacy and public interest activities and has provided expert advice and consultation for Google, Microsoft, Facebook, and other organizations, government agencies, and private interests.

A Framework for Ethics Committees for Reviewing Research Protocols with Privacy and Confidentiality-Related Risks in Electronic Environment

Adarsh K. Gupta, D.O., M.S., FACOFP
Rowan University

Dr. Adarsh K. Gupta, is an AOA board-certified physician in southern New Jersey. He is Chairman of Institutional Review Board of Rowan University, School of Osteopathic Medicine (Rowan-SOM). He is a Professor of Family Medicine at the Rowan-SOM.

He is also the Founding Director of the Center for Medical Weight Loss and Metabolic Control that focuses on improving metabolic disorders (diabetes, hypertension, and hyperlipidemia) and functional disorders (severe arthritis, sleep apnea, knee pain, etc.) with weight management. He is a speaker, consultant, and author who specializes in medical weight loss and metabolic disorders.

Dr. Gupta is also the Center Director for Information Mastery which involves teaching medical students, residents and faculty in medical informatics and evidence-based medicine. Dr. Gupta has interest in technology in medicine, management of chronic diseases, preventive medicine and lifestyle medicine. Dr. Gupta has presented locally, regionally, and nationally on the topics related to Obesity, Weight Management, and Integration of Technology in Medicine.

In addition to his work as a physician, Dr. Gupta also writes online blogs and articles, and has been quoted in multiple newspapers and magazines, including Courier Post, SJ Magazine, The DO Magazine, Star-Ledger, etc. He has also discussed weight management on CBS TV show "Talk Philly." After receiving his bachelor's degree in chemical engineering and Master's degree in Biomedical Engineering from New Jersey Institute of Technology, Dr. Gupta earned his Osteopathic medical degree at University of Medicine and Dentistry of New Jersey - School of Osteopathic Medicine.

Facing the Future: Operational Solutions to the Regulatory Challenges of Big Data Research

Megan Kasimatis-Singleton, J.D., M.B.E., CIP
Johns Hopkins University

Megan Kasimatis Singleton, JD, M.B.E., CIP is the Assistant Dean for Human Research Protection and Director of the Human Research Protection Program (HRPP) at Johns Hopkins University School of Medicine. In this role, she is responsible for oversight and direction of JHM's 7 IRBs. Ms. Singleton is a licensed attorney in Pennsylvania. She earned her law degree from Temple University and her Master's in Bioethics from the University of Pennsylvania.

In addition to her current role in leading the Johns Hopkins Medicine HRPP, she serves as the director of central IRB (CIRB) activities for the Johns Hopkins/Tufts Trial Innovation Center (TIC), leading the charge for innovations in operationalizing single IRB (sIRB) review. In addition to her role as TIC CIRB lead, she is heavily engaged in national efforts to streamline the implementation of sIRB review processes including as a member of the Federal Demonstration Partnership taskforce on sIRB review and as a member of the SMART IRB Harmonization Steering Committee. Ms. Singleton is the Co-Chair of the AER Conference Workshop/Didactic Subcommittee, is an AAHRPP, Inc. site visitor, and is a member of the Steering Committee for AEREO, a consortium designed to advance effective research ethics oversight through empirical research.

Ethical Considerations for the Review of Big Data Research Beyond the Common Rule

Brenda Leong
Future of Privacy Forum

Brenda Leong, CIPP/US, is Senior Counsel and Director of Strategy at the Future of Privacy Forum. She oversees strategic planning of organizational goals, as well as managing the FPF portfolio on biometrics, particularly facial recognition, along with the ethics and privacy issues associated with artificial intelligence. She works on industry standards and collaboration on privacy concerns, by partnering with stakeholders and advocates to reach practical solutions to the privacy challenges for consumer and commercial data uses. Prior to working at FPF, Brenda served in the U.S. Air Force, including policy and legislative affairs work from the Pentagon and the U.S. Department of State. She is a 2014 graduate of George Mason University School of Law.

Shared Responsibility in Ethical Big Data Research

Jacob Metcalf, Ph.D.
Data & Society Research Institute

Jacob (Jake) Metcalf, Ph.D. is a technology ethics researcher and consultant specializing in data analytics and artificial intelligence. He is a Researcher at Data & Society on an NSF-funded multisite project, Pervasive Data Ethics for Computational Research (PERVADE). For this project, he studies how data ethics practices are emerging in environments that have not previously grappled with research ethics, such as industry, conference committees, and civil society organizations. He also studies how design practices can successfully integrate ethical values and principles. Jake also runs a consulting firm, Ethical Resolve, LLC, that provides clients with a range of ethics services, helping clients make well-informed, consistent, actionable and timely business decisions that reflect their values. He lives amongst the redwoods of the Santa Cruz mountains.