

BIG DATA, SMALL DATA, AND THE IMPLICATIONS FOR HUMAN SUBJECTS RESEARCH






AGENDA

Tuesday, April 4, 2017

7:30 AM - 8:30 AM	Registration and Breakfast Registration and Breakfast	◆
8:30 AM - 8:45 AM	Welcome & Introductions	◆
8:45 AM - 10:00 AM	Back to Basics: Does My Project Fall within the Scope of the regulations? Presentation will engage audience in interpreting and applying HHS regulations and OHRP policies such as the definition of research, human subject, and the enumerated exemptions. Speakers: Yvonne Lau, MBBS, MBHL, Ph.D.	◆
10:00 AM - 10:15 AM	Morning Break	◆
10:15 AM - 11:15 AM	Reimagining Healthcare Using Real Time Analytics and Big Data Medicine has entered an era of unprecedented changes, leading towards a revolution that will push us to re-invent health and health (sick) care. Health (care) is being disrupted by 3 trends: sustainability, digital health, and progress. This talk will discuss these trends and the solutions to re-imagine the delivery of healthcare. Speakers: Andre Goy, M.D., M.S.	◆
11:15 AM - 12:15 PM	The Ethics of Incidental Findings and Genomic Sequencing Research Through a series of case studies exploring the thorniest issues in the incidental findings literature, this presentation will how to define the contours of researchers' obligations to return incidental findings. Speakers: Benjamin E. Berkman, JD, MPH	◆
12:15 PM - 1:15 PM	Networking Lunch NOTE: OHRP staff and resources have not be used to develop, promote, or otherwise support this portion of the event.	◆
1:15 PM - 3:00 PM	Let's Review a Protocol Together OHRP staff will present one or more research protocols and invite the audience to review them together using the principles and guidance provided by the HHS regulations and OHRP policies. Speakers: Jaime Hernandez, J.D., M.Be.	◆
3:00 PM - 3:15 PM	Afternoon Break	◆
3:15 PM - 4:00 PM	Conducting Secondary Research with Identifiable Private Information Under the New Regulations Presentation will provide an overview of the changes to the Common Rule as applied to secondary research with identifiable private information. Speakers: Julie Kaneshiro	◆
4:00 PM - 4:15 PM	Wrap-up and Q&A	◆

Wednesday, April 5, 2017

7:00 AM - 8:00 AM	Registration/Breakfast	
8:00 AM - 8:15 AM	Welcome and Opening Remarks	
8:15 AM - 9:15 AM	Big Data, Privacy and the Public Good This presentation overviews some of the contributions and challenges associated with using big data for research purposes. It summarizes the findings of a recent book of the same title as the presentation http://www.dataprivacybook.org/ . It also suggests some useful approaches for the research community. Speakers: Julia Lane	
9:15 AM - 10:15 AM	Overview of the 2018 Changes to the Common Rule Speakers: Julie Kaneshiro	
10:15 AM - 10:30 AM	Break	
10:30 AM - 11:15 AM	The impact of personalized medicine for cancer patients through big and small data. Speakers: Stuart L. Goldberg, M.D.	
11:15 AM - 12:00 PM	Reexamining the Right Not to Know. This lecture will controversially question whether the traditional view that patients have a "right not to know" ("RNTK") genetic information about themselves is still appropriate in a genomic era. Speakers: Benjamin E. Berkman, JD, MPH	
12:00 PM - 1:00 PM	Networking Lunch NOTE: OHRP staff and resources have not be used to develop, promote, or otherwise support this portion of the event.	
1:00 PM - 2:00 PM	Breakout 1A- Big Data, Identifiability, and Deductive Disclosure: Let's Get Real about Risks Identifying risks can be easier for an IRB than assessing their likelihood, and research involving big data has made the exercise even more difficult. Suggestions for approaching the problem will be discussed. Speakers: Dean Gallant	
1:00 PM - 2:00 PM	Breakout 1B - From Human Subjects to Data Subjects: Exploring the Landscape of Internet Research This session will provide an historical overview of Internet research and the ways in which IRBs have responded to the various challenges and opportunities since the mainstream acceptance of the Internet, social media, and big data. Speakers: Elizabeth Buchanan, Ph.D.	
2:00 PM - 2:10 PM	Break	
2:10 PM - 3:10 PM	Breakout 2A - Precision Medicine – A Promissory Note Speakers: Reynold Panettieri, Jr.	
2:10 PM - 3:10 PM	Breakout 2B - Data and the changing impact of social and psychological Risks in SBE Research The presentation will describe the assessment of the various types of risks in social-behavioral research and will include a discussion of the risks and issues associated with the use of social media in research. There will also be time available at the end of the presentation for participant questions and comments. Speakers: Wayne Patterson	

3:10 PM - 3:20 PM	Break	
3:20 PM - 4:20 PM	Breakout 3A - Building a Research Data Security and Management Infrastructure Speakers: Ara Tahmassian, Ph.D.	
3:20 PM - 4:20 PM	Breakout 3B - Issues with data utilization (including social media data) and incidental findings in Speakers: Tracy Ziolek	
4:20 PM - 4:30 PM	Break	
4:30 PM - 5:15 PM	Ask the Feds	
5:15 PM - 5:30 PM	Closing Remarks	