

Working Group Meeting #2
Thought Leader Input and Regulatory Framework
AC Hotel Chicago Downtown
630 N. Rush Street
Chicago, IL
April 24-25, 2018

Meeting goals:

1. Working Group meeting #1 in San Diego focused on mHealth technology, the participants and researchers involved, and the current and future use of mHealth in unregulated research.
2. Working Group meeting #2 will concentrate on identifying current research regulations applicable to research using mobile devices. We will start developing possible policy options, including adapting elements of regulated research for unregulated research.
3. Working Group meeting #3 in Atlanta in October 2018 will focus on ethical aspects of these issues and continue work on policy development.
4. Working Group meeting #4 in Houston in April 2019 will involve drafting and refining the policy options.

Day 1

- 9:00-9:30 Introduction and Meeting Goals
Mark A. Rothstein & John T. Wilbanks
- 9:30-10:30 Preliminary Findings of Aim 1: Thought Leader Interviews
Laura M. Beskow, Ph.D., M.P.H., Vanderbilt University
- 10:30-11:00 Integrating Findings into Aim 2: Policy Development
Mark A. Rothstein & John T. Wilbanks
- 11:00-11:15 Break
- 11:15-12:15 *Regulation of Research*
- Moderator: Kyle B. Brothers, M.D., Ph.D.
- Common Rule and Research with Mobile Devices
Michelle N. Meyer, J.D., Ph.D., Geisinger Health System
- HIPAA Privacy Rule and Research with Mobile Devices
Stacey A. Tovino, J.D., Ph.D., University of Nevada-Las Vegas
- 12:15-1:15 Working Lunch

1:15-3:15 *Regulation of Mobile Health Apps*

Moderator: John T. Wilbanks

FDA Regulation of Mobile Health Apps

Barbara J. Evans, Ph.D., J.D., LL.M., University of Houston
(via Skype)

HHS and FDA Regulatory Agenda

Kevin Chaney, M.G.S.

Senior Program Manager, Office of the National Coordinator of HIT
Department of Health and Human Services

FTC Regulation of Mobile Health Apps

Jennifer K. Wagner, J.D., Ph.D.

Associate Director, Bioethics Research, Center for Translational Bioethics and
Health Care Policy, Geisinger Health System

FCC Regulation of Mobile Health Apps

Yahya Shaikh, M.D., M.P.H.

Senior Advisor for Connected Health, Federal Communications Commission

3:15-3:30 Break

3:30-4:30 *IRBs and Unregulated Research*

Moderator: Laura M. Beskow, Ph.D., M.P.H.

Academic IRBs

P. Pearl O'Rourke, M.D., Partners Healthcare

Independent IRBs

David G. Forster, J.D., M.A., WIRB-Copernicus Group

4:30 Adjourn

Day 2

8:30-9:30 *Privacy, Confidentiality, and Security*

Moderator: Michelle McGowan, Ph.D.

Privacy and Confidentiality

Mark A. Rothstein, J.D., University of Louisville School of Medicine

Security

Andrea M. Matwyshyn, J.D., Ph.D., Northeastern University
(via Skype)

9:30-9:45 Break

9:45-11:15 *Disclosure of Health Information*

Moderator: Megan Doerr, M.S.

Return of Results and Incidental or Secondary Findings

Susan M. Wolf, J.D., University of Minnesota

The Ethical Duties Underlying Return of Results

Ellen Wright Clayton, M.D., J.D., Vanderbilt University

Data Sharing and Publication

Mary Majumder, J.D., Ph.D., Baylor College of Medicine

11:15-11:45 Brainstorming Interim Projects

Mark A. Rothstein & John T. Wilbanks

11:45-12:00 Wrap up and Working Group Meeting #3 (Atlanta, Oct. 25, 2018)

Mark A. Rothstein & John T. Wilbanks

12:00 Adjourn