

**Working Group Meeting #3
Developing Ethical Guidelines and Policy Options**

October 25, 2018
American Hotel, Doubletree by Hilton
160 Ted Turner Drive, NW
Atlanta, GA

Meeting goals:

1. Working Group meeting #1 was held in San Diego in October 2017, and it 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 was held in Chicago in April 2018, and it concentrated 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 crafting and refining the policy options.

8:00-8:30

Introduction and Meeting Goals

Mark A. Rothstein (PI) & John T. Wilbanks (PI)

8:30-10:15

Governance and Oversight

Moderator: Kyle B. Brothers, M.D., Ph.D.
University of Louisville School of Medicine

Independent Research

Megan Doerr, M.S., Principal Scientist, Governance Team, Sage
Bionetworks

Governance, Norms, and Infrastructure

Camille Nebeker, Ed.D., M.S., Assistant Professor, Dep't of Family Med.
& Pub. Health, University of California, San Diego School of Medicine

International Research Norms

Bartha Maria Knoppers, Ph.D., Canada Research Chair in Law and
Medicine, Director, Centre of Genomics and Policy, McGill University

10:15-10:30

Break

10:30-11:30

Other Sources of Oversight

Moderator: Mark Rothstein

Fair Information Practice Principles

Bob Gellman, J.D., Privacy Consultant, Washington, D.C.

General Data Protection Regulation

Edward S. Dove, LL.M., Ph.D., University of Edinburgh

11:30-12:30

Emerging Models of Permission for Research

Moderator: Michelle McGowan, Ph.D.
Cincinnati Children's Hospital

Self-guided Online Consent

John T. Wilbanks, Chief Commons Officer, Sage Bionetworks

Virtual Multimedia Interactive Informed Consent

Fuad Abujarad, PhD., M.Sc., Yale School of Medicine

12:30-1:30

Working Lunch

1:30-2:30

Enrollment and Access to Technology

Moderator: Laura M. Beskow, M.P.H., Ph.D.
Vanderbilt University School of Medicine

Input/Output and Other Issues

S. Malia Fullerton, D.Phil., Associate Professor of Medicine, University of Washington

Minority Enrollment in Unregulated Research

Shawneequa L. Callier, J.D., M.S., Associate Professor, George Washington University School of Medicine and Health Sciences

2:30-4:00

Unregulated Research and Special Populations

Moderator: Megan Doerr, M.S.
Sage Bionetworks

Group Harms and Benefits

Joon-Ho Yu, M.P.H., Ph.D., Senior Fellow, University of Washington School of Medicine

Children and Other Vulnerable Subjects

Kyle B. Brothers, M.D., Ph.D., Endowed Chair in Pediatric Clinical and Translational Research, University of Louisville School of Medicine

Research on Rare Diseases

Aaron J. Goldenberg, Ph.D., M.P.H., Associate Professor of Bioethics, Case Western Reserve University School of Medicine

4:00-4:15

Break

4:15-5:00

Discussion of Working Group Meeting #4 (Houston, April 2019)

Draft recommendations and discussion

Mark Rothstein, John Wilbanks, and Laura Beskow

5:00

Adjourn

Attendees at Working Group Meeting #3

Key Personnel

Mark A. Rothstein, J.D. (PD/PI)	University of Louisville
John T. Wilbanks, B.A. (PD/PI)	Sage Bionetworks
Laura M. Beskow, M.P.H., Ph.D. (co-PI)	Vanderbilt University
Kyle B. Brothers, M.D., Ph.D. (co-PI)	University of Louisville
Megan Doerr, M.S. (co-PI)	Sage Bionetworks
Michelle McGowan, Ph.D. (co-PI)	Cincinnati Children's Hosp.

Working Group (Authors)

Shawneequa L. Callier, J.D., M.S.	George Washington Univ.
Ellen Wright Clayton, M.D., J.D.	Vanderbilt University
Barbara J. Evans, Ph.D., J.D., LL.M.	University of Houston
S. Malia Fullerton, D.Phil.	University of Washington
Aaron J. Goldenberg, Ph.D., M.P.H.	Case Western Reserve Univ.
Bartha Maria Knoppers, Ph.D.	McGill University
Mary Majumder, J.D., Ph.D.	Baylor College of Medicine
Andrea M. Matwyszyn, J.D., Ph.D.	Northeastern University
Michelle N. Meyer, J.D., Ph.D.	Geisinger Health System
Pearl O'Rourke, M.D.	Partners Health
Sharon F. Terry, M.A.	Genetic Alliance
Stacey A. Tovino, J.D., Ph.D.	Univ. of Nevada-Las Vegas
Susan M. Wolf, J.D.	University of Minnesota
Joon-Ho Yu, M.P.H., Ph.D.	University of Washington

Working Group (Discussants)

Kate Black, J.D.	23andMe
Dov Fox, J.D., LL.M.	University of San Diego
Cynthia Geoghegan, B.A.	Patient Advocate
Henry T. Greely, J.D.	Stanford University
Christie Guerrini, J.D., M.P.H.	Baylor College of Medicine
Steve Hershman, Ph.D.	Stanford University
Mark Hurlbert, Ph.D.	Breast Cancer Research Fdn.
Eric T. Juengst, Ph.D.	University of North Carolina
Camille Nebeker, Ed.D., M.S.	Univ. of Cal.-San Diego
Sally Okun, B.S.N., R.N.	PatientsLikeMe
Kevin Patrick, M.D., M.S.	Univ. of Cal.-San Diego
Patricia A. Spears, B.S.	Cancer Research Advocate
Ma'n Zawati, LL.B., LL.M.	McGill University

Guest Speakers

Fuad Abujarad, Ph.D., M.Sc.
Edward S. Dove, LL.M., Ph.D.
Bob Gellman, J.D.

Yale School of Medicine
Univ. of Edinburgh
Privacy Consultant