

The Ethics of Data Access, Use, and Sharing for Human Subjects Research

March 1, 2017

Fenway Room of the Hilton Boston Back Bay
Boston, Massachusetts

- 8:00–8:30 AM Breakfast
- 8:30–8:45 AM Welcome and Overview
Moderator: Elisa A. Hurley, PhD
Summary: Are our current ethical and regulatory schemas adequate to serve the interests and protect the rights of research participants in light of new methods and new expectations for access, use, and sharing of personal data for research purposes?
- 8:45–10:15 AM **Part I:** Perspectives on the value of research employing new approaches to the access, use, and sharing of personal information for research
Moderator: David H. Strauss, MD
Summary: Participants will discuss the scientific potential associated with the range of current and emerging research strategies, methods and technologies involving use of existing data. Alternative perspectives will be offered that present a more cautious assessment of the value of data sharing and open data.
Panelists: Laura Lyman Rodriguez, PhD; Elizabeth Loder, MD, MPH; Sally Okun, RN, MMHS; Irene Pasquetto, MA; Joseph S. Ross, MD, MHS; Nancy Kass, ScD; Adrian F. Hernandez, MD, MHS
- 10:15–10:30 AM Break
- 10:30 AM–12:15 PM **Part II:** Conceptualizing an individual's rights, interests, and expectations with regard to their health and other data
Moderator: Leonard Glantz, JD
Summary: Participants will conceptualize the individual's rights and interests in how information about them is collected, shared, and used for secondary research purposes. Perspectives on potential harm associated with access, use, and sharing of data, including those related to re-identification, will be considered, as will notions of individual rights and interests related to secondary use of de-identified information. Drawing upon the discussion in Part I, participants will ask whether and to what extent patient rights matter given the opportunities presented by science.
Panelists: Alan Rubel, MA, JD, PhD; Suzanne M. Rivera, PhD; Celia Fisher, PhD; Michael Zimmer, PhD; Ifeoma Ajunwa, JD, PhD; Mark Barnes, JD; Elizabeth Buchanan, PhD

- 12:15–12:45 PM Lunch at Forty Dalton Restaurant on first floor of the Hilton Boston Back Bay
- 12:45–2:15 PM **Part III: Implications for consent, authorization, and data stewardship**
Moderator: Jeremy Sugarman, MD, MPH, MA
Summary: A consideration of the requirements for consent is a practical extension of the analyses considered in Parts I and II. Participants will argue for consent or justify its waiver and consider whether alternative approaches to consent effectively respect participant rights, interests, and expectations in the context of new approaches to the use of research data.
Panelists: Alex Capron, LLB; Laura Odwazny, MA, JD; Rebecca Li, PhD; John Wilbanks; Neal Dickert, MD, PhD
- 2:15–2:30 PM Break
- 2:30–3:45 PM **Part IV: Responsibilities for ethical oversight of research involving data access, use, and sharing**
Moderator: Albert J. “AJ” Allen, MD, PhD
Summary: Participants will discuss current and emerging regulations and policy and their implications for the effective oversight of research with secondary data. The roles and responsibilities of the investigator, IRB, institution, sponsor, and journal will be discussed.
Panelists: John R. Baumann, PhD; Brian Herman, MD; Deven McGraw, MPH, JD; Elizabeth Loder, MD, MPH
- 3:45–5:00 PM Summary and next steps
Moderators: Alex Capron, LLB; David Strauss, MD
- 5:15 PM Adjournment