May 1, 2018: Forum Workshop
Joseph B Martin Conference Center, Harvard Medical School

7:30 – 8:30 am  
Registration and Breakfast

8:30 – 8:45 am  
Welcome and Introductions

8:45 – 9:45 am  
Applying the Regulations: Revised Common Rule
This session will engage the audience in discussing application and implementation of the revised Common Rule, including consideration of changes to the exemptions.
  
  Misti Ault Anderson, MS, MA  
  Senior Advisor for Public Health Education, Division of Education and Development, Office for Human Research Protections

9:45 – 10:00 am  
Break

10:00 – 11:00 am  
Secondary Research with Biospecimens
This session will provide an overview of the changes to the Common Rule regarding secondary research with identifiable biospecimens and identifiable private information, including applicable exemptions and relevant aspects of informed consent.
  
  Yvonne Lau, MBBS, MBHL, PhD  
  Director, Division of Education and Development, Office for Human Research Protections

11:00 – 12:00 pm  
Invited Speaker: “Broad Consent” under the New Common Rule and the Survival of the Old “Broad Consent”
In this session local speaker Mark Barnes, JD, LLM, will lead a workshop exploring Broad Consent in relation to the New Common Rule, and whether and how the New Common Rule should be regarded as affecting interpretations of the old, non-regulatory “broad consent for future uses of data and biospecimens” embedded in informed consent forms approved and used both before and after the New Common Rule.
  
  Mark Barnes, JD, LLM  
  Partner, Ropes & Gray LLP  
  Faculty Co-Chair, Multi-Regional Clinical Trials Center, Harvard and BWH  
  Lecturer, Yale Law School and Yale School of Medicine

12:00 – 1:00 pm  
Networking lunch

1:00 – 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.
  
  Misti Ault Anderson, MS, MA  
  Yvonne Lau, MBBS, MBHL, PhD

3:00 – 3:15 pm  
Break

3:15 – 4:15 pm  
Informed Consent Improvements
Jerry Menikoff, MD, JD, will discuss the new requirements and flexibilities in informed consent in the revised Common Rule.
  
  Jerry Menikoff, MD, JD  
  Director, Office for Human Research Protections

4:15 – 4:30 pm  
Wrap-up and Q&A
May 2, 2018: Forum Symposium  
Joseph B Martin Conference Center, Harvard Medical School

7:30 – 8:30 am  Registration and Breakfast

8:30 – 8:45 am  Welcome and Opening Remarks

8:45 – 9:30 am  Keynote: Personalized, Personalized Medicine
During his third year of medical student, David Fajgenbaum, MD, MBA, MSc, became critically ill with idiopathic multicentric Castleman disease (iMCD), spent five months hospitalized, and had his last rites read before chemotherapy saved his life. Between multiple life-threatening relapses, Fajgenbaum began conducting translational research into iMCD and created the Castleman Disease Collaborative Network (CDCN). He is currently in his longest remission ever thanks to a precision treatment that he identified, which had never been used before for iMCD. Fajgenbaum, now a faculty member at UPenn, will offer insights into biomedical research from the unique perspective of a researcher, patient, and advocate.

David Fajgenbaum, MD, MBA, MSc  
Assistant Professor, University of Pennsylvania Perelman School of Medicine  
Associate Director, Orphan Disease Center at UPenn  
Executive Director, Castleman Disease Collaborative Network

9:30 – 9:45 am  Break

9:45 – 10:45 am  Introducing the Reasonable Person Standard as Part of Research Informed Consent: Three Perspectives
This panel will explore the introduction of the Reasonable Person Standard and its impact on research through a discussion with leading academics, practitioners and patient advocates.
Panelists:
Laura Beskow, MPH, PhD  
Professor, Vanderbilt University Center for Biomedical Ethics & Society

John Goldberg, JD, MA, MPhil  
Deputy Dean and Eli Goldston Professor of Law, Harvard Law School

Sally Okun, RN  
Vice President for Policy and Ethics, PatientsLikeMe

Moderator:  
Susan Kornetsky, MPH  
Senior Director, Clinical Research Compliance, Boston Children’s Hospital

10:45 – 11:30 am  From Clinical Consent to Research Consent
This session will explore how looking at research consent from the viewpoint of what takes place in the context of clinical consent can be helpful in understanding the goals of the consent provisions in the revised Common Rule, and how to interpret them.
Jerry A. Menikoff, MD, JD  
Director, Office for Human Research Protections

11:30am – 11:45am  Break
11:45 – 12:30 pm  
**Keynote: Achieving the Multiple Aims of Informed Consent to Research**

The classic answer to the question, “Why informed consent?”, is that it promotes respect for persons by giving prospective research participants the opportunity to choose what will or will not happen to them. But informed consent is much more complicated and multidimensional. Identifying the distinct purposes of informed consent, devising strategies to achieve each, and prioritizing among them will help to achieve the multiple purposes of informed consent.

Steven Joffe, MD, MPH  
Emanuel and Robert Hart Professor of Medical Ethics and Health Policy; Professor of Pediatrics; Chief, Division of Medical Ethics, University of Pennsylvania Perelman School of Medicine

12:30 – 1:15pm  
**Lunch**

1:15 – 2:00pm  
**Afternoon Sessions:**

**Amphitheatre**  
**Session topic forthcoming**

Jordan Smoller, MD, ScD  
MGH Trustees Endowed Chair in Psychiatric Neuroscience; Professor of Psychiatry, Harvard Medical School  
Professor, Department of Epidemiology, Harvard T.H. Chan School of Public Health  
Associate Chief for Research, MGH Department of Psychiatry  
Director of the Psychiatric and Neurodevelopmental Genetics Unit, MGH Center for Genomic Medicine

Megan Morash, RN  
Partners Healthcare Systems

**Rotunda**  
**Novel approaches to enhance the informed consent process for vulnerable populations**

Vulnerable populations pose a unique challenge to obtaining informed consent. This session will highlight some novel approaches currently in use and open discussion for possible innovations in the future.

Jonathan Davis, MD  
Vice-Chair of Pediatrics; Chief of Newborn Medicine; Associate Director of the Clinical and Translational Science Institute, Floating Hospital for Children at Tufts Medical Center  
Professor of Pediatrics, Tufts University School of Medicine

Mark Alexander, MD  
Vice Chairperson, Boston Children’s Hospital IRB  
Associate in Cardiology, Co-Director Exercise Physiology, Boston Children’s Hospital  
Assistant Professor in Pediatrics, Harvard Medical School

2:00 – 2:15 pm  
**Break**
2:15 – 3:00 pm Afternoon Sessions:

Amphitheatre Implementing Informed Consent for Genomic Research in a Large Healthcare System
Mobile technologies have the potential to revolutionize both the way in which individuals monitor their health as well as the way researchers can collect data on participants in clinical studies. The thoughtful development of these systems is essential and must consider designing for maximum impact, social constructs and ecosystems of trust. A case study of one such mHealth study, leveraging Apple’s ResearchKit framework, will be presented and discussed.

John Wilbanks
Chief Commons Officer, Sage Bionetworks

Pearl O’Rourke, MD
Director of Human Research Affairs, Partners Healthcare Systems

Rotunda Session topic forthcoming

David Strauss, MD
Associate Professor of Psychiatry, Columbia University Medical Center
Board member, Public Responsibility in Medicine and Research

3:00 – 3:15 pm Break

3:15 – 4:00 pm Afternoon Sessions:

Amphitheatre Session topic forthcoming

Stephen Latham, JD, PhD
Director, Interdisciplinary Center for Bioethics, Yale University
Faculty Chair, Yale’s Human Subjects Committee
Co-chair, Yale’s Embryonic Stem Cell Research Oversight Committee

Rotunda Ethical risks and remedies in social behavioral research involving genetic testing

Celia B. Fisher, PhD
Marie Ward Doty University Chair in Ethics; Professor of Psychology; Director Center for Ethics Education; Director HIV and Drug Abuse Prevention Research Ethics Training Institute, Fordham University

Melissa Abraham, PhD, MSc
Chair, Partners Human Research Committee
Assistant Professor in Psychiatry, Harvard Medical School
Associate Psychologist, Massachusetts General Hospital
Faculty Associate, Center for Bioethics at Harvard Medical School

4:00 – 4:15 pm Break

4:15 – 5:00 pm Ask the Feds
OHRRP staff will form a panel and answer your questions about regulation and the revised Common Rule. Submit questions throughout the day or bring them to the session to ask in person.

5:00 pm Closing Remarks