

**May 1, 2018: Forum Workshop**

Joseph B Martin Conference Center, Harvard Medical School

7:30 – 8:30 am	<b>Registration and Breakfast</b>
8:30 – 8:45 am	<b>Welcome and Introductions</b>
8:45 – 9:45 am	<p><b>Applying the Regulations: Revised Common Rule</b>  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</p>
9:45 – 10:00 am	<b>Break</b>
10:00 – 11:00 am	<p><b>Secondary Research with Biospecimens</b>  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</p>
11:00 – 12:00 pm	<p><b>Invited Speaker: “Broad Consent” under the New Common Rule and the Survival of the Old “Broad Consent”</b>  In this session local speaker Mark Barnes, JD, LL.M, 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, LL.M  Partner, Ropes &amp; Gray LLP  Faculty Co-Chair, Multi-Regional Clinical Trials Center, Harvard and BWH  Lecturer, Yale Law School and Yale School of Medicine</p>
12:00 – 1:00 pm	<b>Networking lunch</b>
1:00 – 3:00 pm	<p><b>Let’s Review a Protocol Together</b>  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</p>
3:00 – 3:15 pm	<b>Break</b>
3:15 – 4:15 pm	<p><b>Informed Consent Improvements</b>  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</p>
4:15 – 4:30 pm	<b>Wrap-up and Q&amp;A</b>

**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 the University of Pennsylvania, 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 of Clinical Research Compliance, Boston Children's Hospital
- 10:45 – 11:00am **Break**
- 11:00 – 11:45am **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 clarify 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

11:45 – 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

**Breakout Session Block One**

Theme: Biomedical and Beyond	Theme: Pediatric and Vulnerable Populations
<i>Located in the Amphitheatre</i>	<i>Located in the Rotunda</i>
<p><b>Legally authorized representatives - Ethical, Legal and practical issues for Researchers and IRBs.</b>                      Legally Authorized Representatives (LAR) play a critical role in human subject protection as they make decisions for those who are not capable of deciding to participate either by age or cognitive capacity to consent. Definitions of who can be a LAR vary by State and may be complicated by hospital policy, local practice or IRB policy. Further complicating the issue is the multitude of other, similar roles such as surrogate, health care proxy or durable power of attorney. Ethical issues of impaired decision relating to the loss or regaining ability to consent will be discussed. This session will discuss strategies for IRBs and researchers to navigate the many aspects of ensuring that a LAR can appropriately consent on behalf of a participant. through lecture and group discussion.</p> <p>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</p> <p>Patricia Seymour, MA, CCRC, CIP                      Project Director, Associates for IRB/HRPP Solutions (AIS)</p>	<p><b>Facilitating choice in the informed consent process for vulnerable populations</b>                      Under existing regulations, the field has taken a highly rigid and fairly uniform approach to informed consent—one where the information flows unidirectionally, is not clinically informed, and is not influenced by the fact that individuals choosing (or declining) to take late part in research want/need/care about different information. The focus on informed consent has been primarily on the creation of the informed consent document rather than on the process of engagement toward participants’ understanding of their involvement in the research. This session will lecture on these issues, reference the directions the new common rule takes on consent, present the concept of appreciation as a foundation for informed consent, and engage the audience in interactive discussion.</p> <p>David Strauss, MD                      Associate Professor of Psychiatry, Columbia University Medical Center                      Board member, Public Responsibility in Medicine and Research</p> <p>Madelon Baranoski, PhD                      Professor of Psychiatry and Director of Psychological Services, Yale School of Medicine, Law and Psychiatry Division</p>

2:00 – 2:15 pm

**Break**

2:15 – 3:00 pm

**Breakout Session Block Two**

<b>Theme: Biomedical and Beyond</b>	<b>Theme: Pediatric and Vulnerable Populations</b>
<i>Located in the Amphitheatre</i>	<i>Located in the Rotunda</i>
<p><b>Participant Centered Design for Informed Consent</b>                      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.</p> <p>John Wilbanks                      Chief Commons Officer, Sage Bionetworks</p> <p>Pearl O’Rourke, MD                      Director of Human Research Affairs, Partners Healthcare Systems</p>	<p><b>Novel approaches to enhance the informed consent process for vulnerable populations</b>                      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.</p> <p>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</p> <p>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</p>

3:00 – 3:15 pm

**Break**

3:15 – 4:00 pm

**Breakout Session Block Three**

<b>Theme: Biomedical and Beyond</b>	<b>Theme: Pediatric and Vulnerable Populations</b>
<i>Located in the Amphitheatre</i>	<i>Located in the Rotunda</i>
<p><b>Implementing Informed Consent for Genomic Research in a Large Healthcare System</b>                      Implementing Informed Consent in the context of a large healthcare system poses unique challenges and opportunities. In this session speakers Jordan Smoller and Megan Morash will discuss lessons learned from the Partners Biobank and All of Us Research Program.</p> <p>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</p> <p>Megan Morash, RN                      Partners Healthcare Systems</p>	<p><b>Ethical risks and remedies in social behavioral research involving genetic testing</b>                      This session will explore ethical and practical issues related to research on behavioral disorders involving predictive genetic testing in children. Points to consider include genetic literacy in the informed consent process for parents and children; public tendencies toward genetic determinism and decisions regarding return of genetic results to parents and adolescents reaching the age of majority; and related challenges of broad consent and secondary use of identifiable behavioral information and genetic data from research involving socially vulnerable populations.</p> <p>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</p> <p>Melissa Abraham, PhD, MSc                      Director, Research Ethics Consultation Unit, Division of Clinical Research, Massachusetts General Hospital                      Associate Psychologist, Department of Psychiatry, Massachusetts General Hospital                      Assistant Professor, Harvard Medical School                      Faculty Associate, Center for Bioethics, Harvard Medical School</p>

4:00 – 4:15 pm

**Break**

4:15 – 5:00 pm

**Ask the Feds**

OHRP 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**