INSTITUTE OF MEDICINE

National Cancer Policy Forum Workshop
Contemporary Issues in Human Subjects Protections

The Keck Center of the National Academies
500 Fifth Street, NW - Room 100
Washington, DC 20001

February 24, 2014	
7:30 am	**Registration and Breakfast**
8:00 am	**Welcome from the IOM's National Cancer Policy Forum** John Mendelsohn, MD Anderson Cancer Center *Chair, National Cancer Policy Forum* **Overview of the Workshop** Steven Piantadosi, Samuel Oschin Comprehensive Cancer Institute Angela Bradbury, Perelman School of Medicine at the University of Pennsylvania *Planning Committee Co-Chairs*
8:15	**The Current Landscape in Human Subjects Protections** Holly Taylor, Associate Professor, Health Policy and Management, Johns Hopkins Bloomberg School of Public Health and Core Faculty, Johns Hopkins Berman Institute of Bioethics
8:45	**Session 1: The Revised HIPAA Privacy Rule and Researchers' Use of Data** *Moderator: Tom Kean, C-Change* • Melissa Bianchi, Partner, Hogan Lovells • Alice Leiter, Policy Counsel, Health Privacy Project, Center for Democracy & Technology • Brad Malin, Associate Professor of Biomedical Informatics & Vice Chair for Research, School of Medicine, Vanderbilt University **Group Discussion**
10:15	**Break**
10:30	**Session 2: Improving the Informed Consent Process** *Moderator: Laura Cleveland, Patient Advocate, CALGB/Alliance and NCI CIRB* **The Patient Experience** • Laura Cleveland, Patient Advocate, CALGB/Alliance and NCI CIRB **NCI Common Consent Form** • Mary McCabe, Director, Survivorship Program, Memorial-Sloan Kettering Cancer Center

	Challenges and Opportunities to Improve the Informed Consent Process • Terrence Albrecht, Associate Center Director, Barbara Ann Karmanos Cancer Institute, Wayne State University • Laura Cleveland, Patient Advocate, CALGB/Alliance and NCI CIRB • Michael Paasche-Orlow, Associate Professor of Medicine, Boston University • Jeffrey Botkin, Associate Vice President for Research Integrity, University of Utah, and Chair, Secretary's Advisory Committee on Human Research Protections **Group Discussion**
12:45 pm	**Lunch**
1:30 pm	**Session 3: Ethical Challenges of Genome-based Cancer Research** *Moderator: Angela Bradbury, Perelman School of Medicine at the University of Pennsylvania, and Planning Committee Co-Chair* **Overview** • Angela Bradbury, Perelman School of Medicine at the University of Pennsylvania, and Planning Committee Co-Chair • Gail Jarvik, Head and Professor, Division of Medical Genetics, University of Washington School of Medicine • Ellen Wright Clayton, Craig Weaver Professor of Pediatrics and Professor of Law, Vanderbilt Center for Biomedical Ethics and Society • Angela Bradbury, Perelman School of Medicine, University of Pennsylvania • Jeffrey Peppercorn, Director, Duke Cancer Survivorship Center, Associate Professor of Medicine, Division of Medical Oncology, Duke University Medical Center **Group Discussion**
3:45 pm	**Break**
4:00 pm	**Session 4: Patients' Perspectives on Human Subjects Protections in Cancer Research** *Moderator: Patricia A. Ganz, University of California, Los Angeles* • Sharon Terry, Genetic Alliance • Laura Cleveland, Patient Advocate, CALGB/Alliance and NCI CIRB • Deborah Collyar, Founder and President, Patient Advocates In Research **Group Discussion**
5:15 pm	**Reception – 3rd Floor Atrium**

February 25, 2014	
8:00 am	**Breakfast**
8:30 am	**Session 5: Ethical Oversight of Clinical Effectiveness Assessments** *Moderator: Steven Joffe, University of Pennsylvania* **Risk-based Oversight in a Learning Health Care System** • Ruth Faden, Director, Johns Hopkins Berman Institute of Bioethics • Jerry Menikoff, Director, Office for Human Research Protections, Department of Health and Human Services **Oversight of Pragmatic Randomized Trials** • Susan S. Ellenberg, Professor of Biostatistics, University of Pennsylvania School of Medicine **Group Discussion**
10:00 am	**Break**
10:15 am	**Session 6: The Challenges and Successes of Review and Oversight of Multicenter Cancer Studies** *Moderator: Steven Piantadosi, Samuel Oschin Comprehensive Cancer Institute* **Part I: Perspectives of the principal investigator, trial sponsor, and host institution** • Barbara Bierer, Senior Vice President of Research, Brigham and Women's Hospital, and Program Director, Harvard Catalyst Regulatory Knowledge and Support Program • Richard Schilsky, Chief Medical Officer, ASCO **Part II: Perspectives of Local and Central Oversight Bodies** • David Parda, System Chair, Cancer Institute, Radiation Oncology, IRB, Allegheny Health Network • Christopher Daugherty, Professor of Medicine, Chair, Biological Sciences Division Institutional Review Board, University of Chicago **Group Discussion**
12:15 pm	**Workshop Wrap Up** Angela Bradbury, Perelman School of Medicine at the University of Pennsylvania *Planning Committee Co-Chair*
12:30 pm	**Adjourn**