

Appendix 1. Symposium Agenda

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THE PETRIE-FLOM CENTER
FOR HEALTH LAW POLICY, BIOTECHNOLOGY,
AND BIOETHICS AT HARVARD LAW SCHOOL

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Putting Patients at the Center of Research: Opportunities and Challenges for Ethical and Regulatory Oversight

📅 June 29, 2018 10:00 AM - 4:30 PM

📍 Conferences (</events/category/conferences>)

📅 2017-2018 (</events/category/2017-2018>)

📍 Wasserstein Hall, Milstein East ABC

Harvard Law School, 1585 Massachusetts Ave., Cambridge,
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Description

Efforts to place the patient at the center of medical research, spurred by the Affordable Care Act's founding of the Patient Centered Outcomes Research Institute, have begun to change the way clinical research is conceptualized and conducted. Such efforts hold great promise, but also raise potential challenges for ethical oversight. How should oversight bodies approach the presence of patients in potentially unfamiliar research roles, such as investigator? What forms of patient involvement in research, if any, warrant increased scrutiny

from oversight bodies? How do we keep the patient voice from being 'captured' by special interest groups? This symposium brought together a diverse group of patients and community members, policymakers, bioethicists, and regulatory officials to address these and other issues.

This event was free and open to the public.

Agenda

10:00am – 10:45am, Registration

10:45 – 11:00am, Opening Remarks: Introduction to PCOROS—Motivation and Findings

- **Joel Weissman** (<https://www.hcp.med.harvard.edu/faculty/affiliated/joel-weissman-phd>), Deputy Director and Chief Scientific Officer, Center for Surgery and Public Health and Professor of Surgery at Brigham and Women's Hospital; Associate Professor of Health Care Policy, Harvard Medical School
- **I. Glenn Cohen** (<http://petrieflom.law.harvard.edu/about/bio/i-glenn-cohen>), Professor of Law and Faculty Director, the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School

11:00 – 11:45am, PCOROS: Data Gathering

- **Emily Largent** (<http://medicalethicshealthpolicy.med.upenn.edu/faculty-all/emily-largent>), Assistant Professor of Medical Ethics & Health Policy, University of Pennsylvania Perelman School of Medicine and Senior Fellow, Leonard Davis Institute of Health Economics, University of Pennsylvania - *Qualitative interviews and case studies*
- **Eric G. Campbell** (<https://ethics.harvard.edu/people/eric-g-campbell>), Professor of Medicine, Harvard Medical School
Core Faculty, Mongan Institute for Health Policy, Massachusetts General Hospital - *Survey of IRB Chairs*
- **Luke Gelinas** (<http://petrieflom.law.harvard.edu/about/bio/gelinas-luke>), Chairperson, Advarra IRB and Senior Researcher, Petrie-Flom Center - *Delphi Panel and Recommendations*
- Moderator: **Holly Fernandez Lynch** (<http://medicalethicshealthpolicy.med.upenn.edu/faculty-all/holly-fernandez-lynch>), John Russell Dickson, MD Presidential Assistant Professor of Medical Ethics and Health Policy; Assistant Faculty Director of Online Education; Senior Fellow, Leonard Davis Institute of Health Economics, Perelman School of Medicine, University of Pennsylvania

11:45am – 12:45pm, Focus Topic 1: Patients in Non-Traditional Research Roles: Implications for Oversight

Challenge and Recommendations

- **Holly Fernandez Lynch** (<http://medicalethicshealthpolicy.med.upenn.edu/faculty-all/holly-fernandez-lynch>), John Russell Dickson, MD Presidential Assistant Professor of Medical Ethics and Health Policy; Assistant Faculty Director of Online Education; Senior Fellow, Leonard Davis Institute of Health Economics, Perelman School of Medicine, University of Pennsylvania

Response Panel

- **Jane Perlmutter** (http://www.gemini-grp.com/index_files/JP.htm), Cancer Survivor and Patient Advocate - *Comments*
- **Megan Morash**, IRB Chair, Partners Human Research Committee - *Comments*
- **Jeremy Sugarman** (http://www.bioethicsinstitute.org/people/jeremy-sugarman-4?doing_wp_cron=1527606610.4742920398712158203125), Harvey M. Meyerhoff Professor of Bioethics and Medicine, professor of medicine, professor of Health Policy and Management, and deputy director for medicine of the Berman Institute of Bioethics at the Johns Hopkins University - *Comments*
- Moderator: **Joel Weissman** (<http://www.hcp.med.harvard.edu/faculty/affiliated/joel-weissman-phd>), Deputy Director and Chief Scientific Officer, Center for Surgery and Public Health and Professor of Surgery at Brigham and Women's Hospital; Associate Professor of Health Care Policy, Harvard Medical School

12:45 – 1:45pm, Lunch

1:45 – 2:45pm, Focus Topic 2: Patients in Simultaneous Roles?

Challenge and Recommendations

- **Luke Gelinas** (<http://petrieflom.law.harvard.edu/about/bio/gelinas-luke>), Chairperson, Advarra IRB and Senior Researcher, Petrie-Flom Center

Response Panel

- **Martha Carnie**, Senior Patient Advisor, Brigham and Women's Hospital - *Comments from patient*
- **Elisa Hurley** (<https://www.primr.org/newED/hurley/>), Executive Director, PRIM&R - *Comments from IRB*
- **Jean-Christophe Belisle Papon** (<http://petrieflom.law.harvard.edu/fellows/bio/belisle-papon-jean-christophe>), Visiting Researcher, the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at the Harvard Law School - *Comments*
- Moderator: **I. Glenn Cohen** (<http://petrieflom.law.harvard.edu/about/bio/i-glenn-cohen>), Professor of Law and Faculty Director, the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School

2:45 – 3:45pm, Focus Topic 3: Patients and Conflict of Interest: How Can We Keep the Patient's Voice from Being 'Captured'?

Challenge and Recommendations

- **I. Glenn Cohen** (<http://petrieflom.law.harvard.edu/about/bio/i-glenn-cohen>), Professor of Law and Faculty Director, the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School

Response Panel

- **Joe Selby** (<https://www.pcori.org/people/joe-v-selby-md-mph>), Executive Director, Patient-Centered Outcomes Research Institute (PCORI) - *Comments from policy*
- **Andrew Nierenberg** (http://mghcme.org/faculty/faculty-detail/andrew_nierenberg), Thomas P. Hackett, MD, Endowed Chair in Psychiatry, Director of the Bipolar Research Program, and Associate Director of the Depression Clinical and Research Program, Massachusetts General Hospital (MGH); Director of Training and Education, MGH Research Institute - *Comments from PI/bioethicist*
- **Paul McLean** (<http://bioethics.hms.harvard.edu/person/paul-mclean>), ethics associate, Boston Children's Hospital; social media coordinator, Community Ethics Committee; patient/family co-investigator, governance of learning activities in learning healthcare systems (PCORI) - *Comments*
- Moderator: **Emily Largent** (http://medicalethicshealthpolicy.med.upenn.edu/faculty-all/emily_largent), Assistant Professor of Medical Ethics & Health Policy, University of Pennsylvania Perelman School of Medicine and Senior Fellow, Leonard Davis Institute of Health Economics, University of Pennsylvania

3:45 – 4:00pm, Closing Remarks: Where do we go from here?

- **Joel Weissman** (<http://www.hcp.med.harvard.edu/faculty/affiliated/joel-weissman-phd>), Deputy Director and Chief Scientific Officer, Center for Surgery and Public Health and Professor of Surgery at Brigham and Women's Hospital; Associate Professor of Health Care Policy, Harvard Medical School

4:00 – 4:30pm, Networking Reception

Part of the [Patient-Centered Outcomes Research Oversight Study \(PCOROS\)](http://petrieflom.law.harvard.edu/research/pcoros) (<http://petrieflom.law.harvard.edu/research/pcoros>).

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