2021 OHRP EXPLORATORY WORKSHOP

Review of Third-Party Research Risk: Is There a Role for IRBs?

Friday | September 24, 2021 | 9:30AM - 4:00PM ET

Live Webcast from Bethesda, Maryland

DRAFT AGENDA

Time	Sessions
9:45 AM – 10:00 AM	**Welcome**
10:00 AM – 12:35 PM	**Session I: What Do We Mean by Third Parties in Research? What Rights and Protections, if Any, Might They Merit?** **Moderator:** Nir Eyal, Ph.D; *Henry Rutgers Professor of Bioethics, Director of the Center for Population–Level Bioethics (CPLB), Department of Health Behavior, Society and Policy Rutgers University* Historically, the field of research ethics has focused on the idea of protections for research subjects. However, sometimes the conduct of research can have an impact on people outside of the study; these individuals are sometimes referred to as third parties. This session will focus on who impacted parties might be and what types of risks they might face in various types of research. Panelists will consider whether researchers and the research enterprise have a responsibility to protect them and if so, in what capacity.
10:00 AM	**Session I Introduction** Nir Eyal, Ph.D; *Henry Rutgers Professor of Bioethics, Director of the Center for Population–Level Bioethics (CPLB), Department of Health Behavior, Society and Policy Rutgers University*
10:05 AM	**Who Are Third Parties Impacted by Research?** **a. Clinical Research (Infectious Diseases)** Donn Colby, M.D., MPH; *Research Physician, U.S. Military HIV Research Program (MHRP), Henry M. Jackson Foundation for the Advancement of Military Medicine* **b. Research Studies That Do Not Directly Involve Human Subjects** Daniel K. Nelson, MSc, CIP; *Emeritus, U.S. Environmental Protection Agency, Emeritus Professor of Social Medicine and Pediatrics, Faculty Associate, Center for Bioethics, University of North Carolina at Chapel Hill* **c. Social and Behavioral Research** David W. Lounsbury, Ph.D; *Associate Professor, Epidemiology & Population Health, Associate Director, Patient-Centered Outcomes Research Training, Department of Epidemiology & Population Health, Division of Health Behavior Research and Implementation Science, Albert Einstein College of Medicine*
10:50 AM	**Is it Acceptable to Expose Third Parties to Risks Related to the Conduct of Research, and if so, Are There Limits to the Acceptable Level of Risk?** Seema K. Shah, J.D.; *Associate Professor of Pediatrics (Advanced General Pediatrics and Primary Care) and School of Law, Founder's Board Professor of Medical Ethics, Department of Pediatrics, Northwestern University Feinberg School of Medicine, Associate Director of Research Ethics, Lurie Children's Hospital*
11:05 AM	**How Does the Public Perceive Risks?** Tamar Krishnamurti, Ph.D; *Assistant Professor of Medicine and Clinical and Translational Science, University of Pittsburgh School of Medicine*
11:20 AM	**If Proposed Research Stands to Put Third Parties at Risk of Harm, Should Researchers Seek Their Consent?** Holly Fernandez Lynch, J.D., MBe; *John Russell Dickson, MD Presidential Assistant Professor of Medical Ethics, Department of Medical Ethics and Health Policy, Perelman School of Medicine (PSOM), University of Pennsylvania, Assistant Faculty Director of Online Education, Department of Medical Ethics and Health Policy, Perelman School of Medicine, University of Pennsylvania, Founder and Chair, The Consortium to Advance Effective Research Ethics Oversight (AEREO)*

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11:35 AM	**Session I Panel Discussion**
12:35 PM – 1:30 PM	**Lunch**
1:30 PM - 4:00 PM	**Session II: Do IRBs Have a Role in the Review of Third-Party Research Risks and if so, When?** **Moderator:** Leslie E. Wolf, J.D., MPH; *Interim Dean, Distinguished University Professor of Law, Georgia State University College of Law* Currently, there are no regulatory requirements to protect third parties and there is not an accepted structure to support a collective effort to do so. This session will explore the idea of expanding protections to cover third parties in some circumstances. Panelists will discuss whether and what support for this idea already exists in the field of research ethics and whether institutional review boards (IRBs) have a role to play in oversight of such protections should they be warranted.
1:30 PM	**Session II Introduction** Leslie E. Wolf, J.D., MPH; *Interim Dean, Distinguished University Professor of Law, Georgia State University College of Law*
1:35 PM	**Research Risks to Third Parties: Are These "Social Risks" That Require a Different Conceptual Approach?** Jonathan Herington, Ph.D; *Assistant Professor, Department of Philosophy, Assistant Director, Graduate Education and Post-doctoral Affairs, University of Rochester*
1:50 PM	**Addressing Risks to Third Parties in Research Through Community Engagement – Experience From Australia's Eliminate Dengue Program** Jim Lavery, Ph.D; *Hilton Chair in Global Health Ethics, Professor, Hubert Department of Global Health, Rollins School of Public Health, Emory University*
2:05 PM	**What Role Should IRBs Have in Protecting Third Parties?** Jonathan Kimmelman, Ph.D; *James McGill Professor in the Biomedical Ethics Unit / Social Studies of Medicine, STREAM Research Group, Interim Director, Division of Ethics and Policy, School of Population and Global Health*
2:20 PM	**Reviewing Third-Party Risks: A Proposed Framework for IRBs (and Researchers)** David B Resnik, J.D. Ph.D; *Bioethicist and Senior Ethics Specialist, Adjunct Professor of Philosophy and Religion, North Carolina State University, National Institute of Environmental Health Sciences, National Institutes of Health*
2:35 PM	**Are IRBs the Right Oversight Bodies for Protecting Third Parties?** Daniel M. Hausman, Ph.D; *Research Professor, Center for Population-Level Bioethics, Rutgers University*
2:50 PM	**Session II Panel Discussion**
3:55 pm	**Closing**