2021 OHRP EXPLORATORY WORKSHOP

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

Friday | September 24, 2021 | 9:45AM - 4:00PM ET

Live Webcast from Bethesda, Maryland

(No registration required)

AGENDA

Time	Sessions
9:45 AM – 10:00 AM	**OHRP 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?** The research community has generally focused on the protection of human research subjects as defined by the Common Rule. However, sometimes the conduct of research can have an impact on people who are third parties and who do not meet the definition of human subjects. This session will explore who some of the impacted parties are and what types of risks they might face in various types of research. It will not include those third parties whose risks arise from the knowledge gained through the research. Panelists will consider whether researchers and the research community have a responsibility to protect third parties and if so, in what capacity.
10:00 AM	**Session I Overview and Introduction of Speakers** **Moderator:** Nir Eyal, PhD; *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. Research Studies That Do Not Directly Involve Human Subjects** Daniel Nelson; *Emeritus Director, Human Research Protocol Office, U.S. Environmental Protection Agency, Emeritus Professor of Social Medicine and Pediatrics, University of North Carolina at Chapel Hill* **b. Third-Party Risk in Clinical Research Trials** Donn Colby, MD, MPH; *Research Physician, US Military HIV Research Program (MHRP)* **c. Ensuring Privacy, Building Trust: Collecting, Processing, and Sharing Third-Party Information in Social and Behavioral Health Research** David W. Lounsbury, PhD; *Associate Professor, Epidemiology & Population Health, Division of Health Behavior Research and Implementation Science, Albert Einstein College of Medicine*
10:50 AM	**Ethical Considerations for Third-Party Risk in Research** Seema K. Shah, JD; *Founder's Board Professor of Medical Ethics, Associate Professor of Pediatrics, Lurie Children's Hospital & Northwestern University*
11:05 AM	**Limiting Non-Consenting Third Parties to Reasonable Research Risks** Holly Fernandez Lynch, JD, MBe; *John Russel Dickson, MO Presidential Assistant Professor of Medical Ethics, Department of Medical Ethics and Health Policy, Perelman School of Medicine (PSOM), University of Pennsylvania, Founder and Chair, The Consortium to Advance Effective Research Ethics Oversight (www.AEREO.org)*
11:20 AM	**Public Risk Perception and the Creation of Clear Communications** Tamar Krishnamurti, PhD; *Assistant Professor of Medicine and Clinical & Translational Science, Division of General Internal Medicine, University of Pittsburgh*
11:35 AM	**Session I Panel Discussion** Third parties are not directly involved in the research, but they may still incur risk of harm. What are these risks and how may the public or third parties perceive them? Does the research community have a responsibility to protect third parties from potential harms? Are there relevant moral or legal theories that support a charge to protect third parties in research?

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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?** 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 Overview and Introduction of Speakers** **Moderator:** Leslie E. Wolf, JD, MPH; *Distinguished University Professor and Professor of Law, Georgia State University College of Law and School of Public Health*
1:35 PM	**Do Research Risks to Third Parties Require a Different Conceptual Approach?** Jonathan Herington, PhD; *Assistant Professor of Philosophy, University of Rochester*
1:50 PM	**What if All Ethical Implications of Research Could Be Taken Seriously? Insights and Opportunities from Stakeholder Theory** James Lavery, PhD; *Conrad N. Hilton Chair in Global Health Ethics, Professor, Hubert Department of Global Health, Rollins School of Public Health, Emory University*
2:05 PM	**Why (and How) Bystander Protections Make for Good Ethics and Policy** Jonathan Kimmelman, PhD; *James McGill Professor of Medical Ethics, McGill University*
2:20 PM	**Reviewing Third-Party Risks: A Proposed Framework for IRBs (and Researchers)** David B. Resnik, JD, PhD; *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, PhD; *Research Professor, Center for Population-Level Bioethics, Rutgers University*
2:50 PM	**Session II Panel Discussion** There are many types of research that can pose risk to third parties, including non-human subjects research that typically does not fall under the oversight of IRBs. If the research community has a responsibility towards protecting third parties in research, who should be involved? Would IRBs have a part to play in this effort and if so, how? Should IRBs review and consider protections for third parties? What might be their limitations and how should these be dealt with?
3:55 PM	**Closing**

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