

2021 OHRP EXPLORATORY WORKSHOP

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

FRIDAY, SEPTEMBER 24, 2021



Office for
Human Research
Protections

PROGRAM BOOK

INTRODUCTION

BACKGROUND

The rapidly changing landscape of biomedical and health-related behavioral research continues to present diverse challenges for adequately reviewing and appropriately regulating research to best protect human research subjects. Charged with the mission of providing leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS), the Office for Human Research Protections (OHRP) endeavors to keep abreast of these challenges with the long-term goal of developing meaningful policy guidance that responds to them. OHRP's Division of Education and Development (DED) promotes education and outreach on the protection of human subjects in research. DED created the OHRP Exploratory Workshop to provide a platform for collegial intellectual exchanges within the research community to promote exploration of topics of interest that hinge on the Federal regulations for human subjects protection.

The conduct of research can have an impact on people who are third parties and who do not meet the definition of human subjects in the Common Rule. This OHRP Exploratory Workshop explores research risks that may impact these third parties.

OBJECTIVES

The purpose of OHRP's Exploratory Workshop is to provide a platform for open dialogue and exchange of ideas between stakeholders in the regulated community. This workshop on third-party research risks will:

- Identify third parties impacted by research and consider what types of risks they might face in a variety of studies;
- Consider whether researchers and the research community have a responsibility, moral or otherwise, to protect third parties and, if so, in what capacity;
- Review real-world examples for potential protections against research risks to third parties; and
- Reflect on the role of institutional review boards (IRBs) for protecting third parties.

AGENDA

| Time | Sessions |
|---------------------|--|
| 9:45 AM – 10:00 AM | OHRP Welcome |
| 10:00 AM – 12:35 PM | <p>Session I: What Do We Mean by Third Parties in Research? What Rights and Protections, if Any, Might They Merit?</p> <p>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.</p> |
| 10:00 AM | <p>Session I Overview and Introduction of Speakers</p> <p>Moderator: Nir Eyal, PhD; <i>Henry Rutgers Professor of Bioethics, Director of the Center for Population–Level Bioethics (CPLB), Department of Health Behavior, Society and Policy, Rutgers University</i></p> |
| 10:05 AM | <p>Who Are Third Parties Impacted by Research?</p> <p>a. Research Studies That Do Not Directly Involve Human Subjects Daniel Nelson; <i>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</i></p> <p>b. Third-Party Risk in Clinical Research Trials Donn Colby, MD, MPH; <i>Research Physician, US Military HIV Research Program (MHRP)</i></p> <p>c. Ensuring Privacy, Building Trust: Collecting, Processing, and Sharing Third-Party Information in Social and Behavioral Health Research David W. Lounsbury, PhD; <i>Associate Professor, Epidemiology & Population Health, Division of Health Behavior Research and Implementation Science, Albert Einstein College of Medicine</i></p> |
| 10:50 AM | <p>Ethical Considerations for Third-Party Risk in Research</p> <p>Seema K. Shah, JD; <i>Founder's Board Professor of Medical Ethics, Associate Professor of Pediatrics, Lurie Children's Hospital & Northwestern University</i></p> |
| 11:05 AM | <p>Limiting Non-Consenting Third Parties to Reasonable Research Risks</p> <p>Holly Fernandez Lynch, JD, MBe; <i>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)</i></p> |
| 11:20 AM | <p>Public Risk Perception and the Creation of Clear Communications</p> <p>Tamar Krishnamurti, PhD; <i>Assistant Professor of Medicine and Clinical & Translational Science, Division of General Internal Medicine, University of Pittsburgh</i></p> |
| 11:35 AM | <p>Session I Panel Discussion</p> <p>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?</p> |

AGENDA

| Time | Sessions |
|--------------------|--|
| 12:35 PM – 1:30 PM | Lunch |
| 1:30 PM – 4:00 PM | <p>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 the oversight of such protections should they be warranted.</p> |
| 1:30 PM | <p>Session II Overview and Introduction of Speakers Moderator: Leslie E. Wolf, JD, MPH; <i>Distinguished University Professor and Professor of Law, Georgia State University College of Law and School of Public Health</i></p> |
| 1:35 PM | <p>Do Research Risks to Third Parties Require a Different Conceptual Approach? Jonathan Herington, PhD; <i>Assistant Professor of Philosophy, University of Rochester</i></p> |
| 1:50 PM | <p>What if All Ethical Implications of Research Could Be Taken Seriously? Insights and Opportunities from Stakeholder Theory James Lavery, PhD; <i>Conrad N. Hilton Chair in Global Health Ethics, Professor, Hubert Department of Global Health, Rollins School of Public Health, Faculty of the Center for Ethics, Emory University</i></p> |
| 2:05 PM | <p>Why (and How) Bystander Protections Make for Good Ethics and Policy Jonathan Kimmelman, PhD; <i>James McGill Professor of Medical Ethics, McGill University</i></p> |
| 2:20 PM | <p>Reviewing Third-Party Risks: A Proposed Framework for IRBs (and Researchers) David B. Resnik, JD, PhD; <i>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</i></p> |
| 2:35 PM | <p>Are IRBs the Right Oversight Bodies for Protecting Third Parties? Daniel M. Hausman, PhD; <i>Research Professor, Center for Population-Level Bioethics, Rutgers University</i></p> |
| 2:50 PM | <p>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?</p> |
| 3:55 PM | Closing |

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: Introduction



Nir Eyal, PhD (Moderator)

Henry Rutgers Professor of Bioethics, Director of the Center for Population-Level Bioethics (CPLB), Department of Health Behavior, Society and Policy, Rutgers University

Nir Eyal is the inaugural Henry Rutgers Professor of Bioethics at Rutgers University. He founded and directs Rutgers's Center for Population-Level Bioethics, with appointments at the School of Public Health and the Department of Philosophy. Dr. Eyal's work covers many areas of research ethics and population-level bioethics, including ethics in emerging infection trial vaccine trials, ethics of high-risk trials, and the ethics of disaster response. Eyal's work appeared in *Science*, *PNAS*, *NEJM*, *Lancet*, *BMJ*, and the leading bioethics venues. He is a coauthor of a WHO report, and has co-edited many volumes and journal symposia, as well as the Oxford University Press series *Population Level Bioethics*. Eyal is the recipient of multiple awards from NIH, Wellcome, NSF, and other sources. He edited three journal symposia and wrote multiple articles on the problem of protecting "third parties" or "bystanders" in medical and scientific research.

10:05 AM: Research Studies That Do Not Directly Involve Human Subjects

Challenges and uncertainties frequently arise with studies that do not meet the regulatory definition of human subjects research, or involve people who are not human subjects, but may still be impacted. Using a series of case examples from environmental research and elsewhere, the presenter will outline the challenges of protecting people in this kind of research. Issues to be explored include how third parties are identified, how risk is assessed, and whether third parties can be adequately protected within existing frameworks.



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

Recently retired, Daniel Nelson is Emeritus Director of the Human Research Protocol Office for the U.S. Environmental Protection Agency, and Emeritus Professor of Social Medicine and Pediatrics at the University of North Carolina-Chapel Hill. Over the course of his career, Nelson played a leading role in national initiatives that shaped the field of human research protections, serving as president of the Applied Research Ethics National Association; charter member of the Council for Accreditation and site visitor for AAHRPP; charter member of the Council for Certification of IRB Professionals; and consultant to the federal OHRP. For ten years he chaired a subcommittee of the Secretary's Advisory Committee on Human Research Protections (SACHRP), advising DHHS on the regulations that govern this area. In 2013 Nelson was honored by Public Responsibility in Medicine and Research (PRIMR) with the ARENA Legacy Award, for leadership and contributions to the field of research ethics.

10:20 AM: Third-Party Risk in Clinical Research Trials

Clinical research for preventing the spread of infectious diseases, such as HIV and Zika, commonly presents risks to third parties. Researchers conducting these studies in foreign countries are particularly well-positioned to share their experience and perspectives on managing third-party risks from these clinical trials.



Donn Colby, MD, MPH

Research Physician, US Military HIV Research Program (MHRP)

Dr. Donn Colby is a Research Physician at the U.S. Military HIV Research Program (MHRP). Based in Seattle, WA, he supervises collaborative studies with Joint Base Lewis-McChord (JBLM) in Washington State and contributes to clinical protocols implemented in Asia. Prior to joining MHRP in 2019, he was co-investigator on the RV254 trial of acute HIV infection at the Thai Red Cross AIDS Research Centre in Bangkok, Thailand. Dr. Colby received his B.A. in Biology at Johns Hopkins University and his M.D. at the State University of New York at Stony Brook. He did his internal medicine residency training and Masters in Public Health at the University of Washington in Seattle. Dr. Colby's has published extensively on the epidemiology of HIV in Southeast Asia, clinical outcomes among people living with HIV, the implementation of preexposure prophylaxis (PrEP), and clinical trials aiming to cure HIV infection.

10:35 AM: Ensuring Privacy, Building Trust: Collecting, Processing, and Sharing Third-Party Information in Social and Behavioral Health Research

A great deal of social and behavioral research involves studying human behavior through individuals' relationships and interactions within familial, social, and cultural groups. Social behavioral researchers frequently find themselves collecting, accessing, or using information of third parties. The presenter will review research studies social behavioral scientists conduct that may create risks to third parties, including troubling questions about privacy, and explain the conceptual challenges with identifying such individuals as human subjects, third parties, or something in between such as "secondary subjects."



David W. Lounsbury, PhD

Associate Professor, Epidemiology & Population Health, Division of Health Behavior Research and Implementation Science, Albert Einstein College of Medicine, Bronx, NY USA

A community psychologist and psycho-oncologist, Dr. Lounsbury's domestic and international research is directed towards implementation of health services interventions and community-based interventions in prevention and control of chronic health illnesses, including cancer, diabetes/obesity, and HIV/AIDS, with a focus on the needs of medically underserved populations. He applies ecologically-grounded social science methodologies, such as participatory action research and system dynamics modeling, as a means to explore and assess complex, multi-level, problems in health care delivery.

10:50 AM: Ethical Considerations for Third-Party Risk in Research

Third parties have received limited attention in the ethics literature or regulations. Accordingly, it is unclear whether or how ethical safeguards for research participants should extend to third parties. This presentation will address consent for third-party risks and its limitations and situate debates over how much third-party risk should be tolerated within the larger, ongoing debate about whether there is an upper limit of risk in research.



Seema K. Shah, JD

Founder's Board Professor of Medical Ethics, Associate Professor of Pediatrics, Lurie Children's Hospital & Northwestern University

Seema K. Shah, JD is the Founder's Board Professor of Medical Ethics and the Director of Research Ethics at Lurie Children's Hospital. She is an Associate Professor of Pediatrics at Northwestern University Feinberg School of Medicine, with a courtesy appointment at Northwestern's Pritzker School of Law. Professor Shah is an international expert in the fields of pediatrics and global health research ethics, as well as on legal and ethical issues in the determination of death. She has published more than 70 articles in the medical, bioethics, and legal literatures and is the co-author of a book on Research Ethics Consultation. She has lectured on these topics around the world and had numerous media mentions and appearances, including in the Wall Street Journal, the New York Times, and PBS NewsHour. Professor Shah attended Stanford University for her undergraduate and law degrees and completed a fellowship in bioethics at the National Institutes of Health (NIH) Clinical Center. She clerked in federal district court in Sacramento, California. Shah was previously on faculty at the University of Washington/Seattle Children's Hospital and at the NIH Clinical Center Department of Bioethics. Finally, Professor Shah has a distinguished record of service, including chairing an NIH committee on ethical considerations in conducting Zika virus human challenge trials and serving as an expert member of a World Health Organization working group to develop key criteria for human challenge trials to address COVID-19 and beyond.

11:05 AM: Limiting Non-Consenting Third Parties to Reasonable Research Risks

It is not always practicable or desirable to seek consent from third parties likely to be exposed to research risk. In these cases, should the lack of consent limit the extent of acceptable risk to third parties - and if so, how? The presenter will discuss analogies to permissible risks for non-consenting research subjects and, beyond the research setting, permissible harms under tort law, concluding that it is sometimes acceptable to expose non-consenting third parties to greater than minimal research risk.



Holly Fernandez Lynch, JD, MBE

John Russel Dickson, MD 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)

Holly Fernandez Lynch, JD, MBE, is the John Russell Dickson, MD Presidential Assistant Professor of Medical Ethics in the Department of Medical Ethics and Health Policy at the Perelman School of Medicine, University of Pennsylvania. Her scholarship focuses on clinical research ethics, access to investigational medicines, Food and Drug Administration policy, and the ethics of gatekeeping in health care. She is founder and co-chair of the Consortium to Advance Effective Research Ethics Oversight (AEREO), which aims to understand, evaluate, and improve IRB quality and effectiveness through empirical research. Prior to joining Penn, Professor Fernandez Lynch was Executive Director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. She previously worked as an attorney in private practice focused on pharmaceuticals regulation at Hogan & Hartson, as a bioethicist at the NIH's Division of AIDS, and as a senior policy and research analyst with President Obama's Commission for the Study of Bioethical Issues.

11:20 AM: Public Risk Perception and the Creation of Clear Communications

Psychologists study the judgments people make when characterizing risks associated with events over which they do not have direct control. This knowledge could help the research community understand how best to conceptualize research risks to third parties and communicate this information to the potentially affected public.



Tamar Krishnamurti, PhD

Assistant Professor of Medicine and Clinical & Translational Science, Division of General Internal Medicine, University of Pittsburgh

Tamar Krishnamurti, PhD is an Assistant Professor of Medicine and Clinical and Translational Science at the University of Pittsburgh. Dr. Krishnamurti draws on (and develops) methods in the social and decision sciences, working with cross-disciplinary experts and community members, to examine problems at the intersection of health, risk, technology, and the environment. Her most recent research focus has been on risk identification, communication, and intervention for maternal health using mobile technologies. At the University of Pittsburgh, Dr. Krishnamurti leads the Behavioral Health arm of the Center for Research on Behavioral Health, Media, & Technology and is a co-founder of the FemTech Collaborative, housed within the Center for Women's Health Research and Innovation.

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?

Currently, there are no regulatory requirements to protect third parties and there is not a recognizable structure to support a collective effort to do so. This session will draw on real-world examples to 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 the oversight of such protections should they be warranted.

1:00 PM: Introduction



Leslie E. Wolf, JD, MPH (Moderator)

*Distinguished University Professor and Professor of Law,
Georgia State University College of Law and School of Public Health*

Leslie Wolf is Distinguished University Professor and Professor of Law at Georgia State University College of Law and the School of Public Health. She served as interim dean of the College (2019-2021) and as director of the Center for Law, Health & Society (2014-2019). Professor Wolf is a leading national scholar in health law, public health and ethics, with a focus on research ethics. She has conducted research on confidentiality risks and protections with a particular focus on Certificates of Confidentiality, research involving biospecimens, conflicts of interest, and IRB guidance, which has been funded by the National Institutes of Health and the Greenwall Foundation. From 2016-2021, Professor Wolf was a member of the Secretary's Advisory Committee on Human Research Protections (SACHRP). She continues to serve on SACHRP's Subcommittee on Harmonization. She previously served on the Centers for Disease Control and Prevention's Ethics Subcommittee to the Advisory Committee to the Director.

1:35 PM: Do Research Risks to Third Parties Require a Different Conceptual Approach?

Many kinds of research can impose risks upon third parties, including research traditionally outside the scope of IRB review. Moreover, human subjects research regulations rely on principles of interpersonal ethics (respect for participant autonomy, favorable risk-benefit ratio) that may be difficult to satisfy in the context of widely-distributed social risks about which affected parties may reasonably disagree. Are third-party risks better conceptualized using frameworks from political philosophy? What can theorizing about justice tell us about the challenges and opportunities with respect to regulating third-party risk?



Jonathan Herington, PhD

Assistant Professor of Philosophy, University of Rochester

Jonathan Herington is an Assistant Professor of Philosophy at the University of Rochester. His research focuses on the political philosophy of science, health and technology. He applies the tools of political philosophy to issues arising in research ethics, the ethics of machine-learning algorithms, public health ethics, and environmental governance. Previously he was an Assistant Professor in the Department of Philosophy at Kansas State University and a Research Fellow in the Medicine, Ethics, Society and History unit of the University of Birmingham. He completed his PhD in the School of Philosophy, at the Australian National University.

1:50 PM: What If All Ethical Implications of Research Could Be Taken Seriously? Insights and Opportunities from Stakeholder Theory

The paradigm for the regulation of research with human subjects embodied in the Common Rule is notable for its exclusive focus on risks to research participants. The decision to view other ethical implications of research, beyond those affecting individual research participants, as “out of scope” of the Common Rule policy, reflects administrative and regulatory management concerns more than ethical concerns. In this presentation I will argue that stakeholder theory offers a way to imagine a broader view of research ethics that is consistent with the core purpose of the Common Rule as a policy of Institutional accountability. I will discuss the implications for IRBs with some case examples of research in which the main ethical concerns lie beyond the protection of individual research participants.



James Lavery, PhD

Conrad N. Hilton Chair in Global Health Ethics, Professor, Hubert Department of Global Health, Rollins School of Public Health, Faculty of the Center for Ethics, Emory University

Jim Lavery is the inaugural Conrad N. Hilton Chair in Global Health Ethics, Professor in the Hubert Department of Global Health in the Rollins School of Public Health, and Faculty of the Center for Ethics, Emory University, Atlanta, Georgia. Prior to Emory he held positions at the National Institutes of Health, and at St. Michael's Hospital and the University of Toronto. He is a Fellow of the Hastings Center and the 2017 recipient of the Global Forum for Bioethics in Research Award for Contributions to Progress in International Research. He is a member of the Board of Directors of the Council for Health Research for Development (COHRED) USA, Chair of the Scientific and Technical Advisory Committee of the Health Campaign Effectiveness Coalition at the Task Force for Global Health in Atlanta, and a member of the Bioethics Advisory Panel of Pfizer, Inc.

2:05 PM: Why (and How) Bystander Protections Make for Good Ethics and Policy

Many would agree that IRBs do not function only to ensure regulatory compliance, but also serve to safeguard the ethics of research and protection of humans in research. If the conduct of research puts third parties directly at risk, IRBs – as a recognized gatekeeper for protecting humans in research – seem to have a role to play.



Jonathan Kimmelman, PhD

James McGill Professor of Medical Ethics, McGill University

Jonathan Kimmelman, PhD, is James McGill Professor of Biomedical Ethics at McGill University, and directs the Biomedical Ethics Unit as well as his own research group, STREAM (Studies in Translation, Ethics and Medicine). Kimmelman's research centers on ethical policy and scientific dimensions of clinical development. Kimmelman received the Maud Menten New Investigator Prize (2006), a CIHR New Investigator Award (2008), a Humboldt Bessel Award (2014), and was elected a Hastings Center Fellow (2018). He has sat on various advisory bodies within the U.S. NHLBI and NIAID, served for four tours of duty on U.S. National Academies of Medicine committees, and chaired the International Society of Stem Cell Research Guidelines for Stem Cell Research and Clinical Translation revision task force 2015-16. His research has been covered in major media outlets, including NPR's All Things Considered, STATNews, and Nature. Kimmelman is deputy editor at Clinical Trials, and associate editor at Cell Med.

2:20 PM: Reviewing Third-Party Risks: A Proposed Framework for IRBs (and Researchers)

The federal research regulations provide no guidance for IRB review of risks to third parties (other than fetuses) who are directly impacted by human subjects research, but IRBs have ethical and legal obligations to address these risks. In this presentation, I will propose a framework for reviewing risks to identifiable third parties that involves four steps: 1) identifying risks; 2) assessing risks; 3) managing risks; and 4) communicating risks. I will also apply the framework to several real-world examples of epidemiological and clinical studies involving risks to third parties.



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*

David B. Resnik is a Bioethicist at the National Institute of Environmental Health Sciences, National Institutes of Health. Dr. Resnik has an M.A. and Ph.D. in philosophy from the University of North Carolina at Chapel Hill, a J.D. from Concord University School of Law, and a B.A. in philosophy from Davidson College. Dr. Resnik was an Associate and Full Professor of Medical Humanities at the Brody School of Medicine at East Carolina University (ECU) from 1998 to 2004, and an Associate Director of the Bioethics Center at ECU and University Health Systems from 1998 to 2004. Dr. Resnik was Assistant and Associate Professor of Philosophy at the University of Wyoming (UW) from 1990 to 1998, and Director of the Center for the Advancement of Ethics at UW from 1995 to 1998. Dr. Resnik has published over 300 articles and 10 books on various topics in philosophy and bioethics and is a Fellow of the American Association for the Advancement of Science. He serves on several editorial boards and is an Associate Editor of the journal *Accountability in Research*.

2:35 PM: Are IRBs the Right Oversight Bodies for Protecting Third Parties?

These are grounds for enabling IRBs to take into account risks to third parties of the research process that are similar to those imposed on research subjects, especially since third parties are generally unable to consent to the research. IRBs should however continue to be prohibited from considering “possible long-range effects of applying knowledge gained in the research”. IRBs are not well placed either to make moral appraisals of the results of research and their consequences or to determine whether research is a prudent use of limited resources.



Daniel M. Hausman, PhD

Research Professor, Center for Population-Level Bioethics, Rutgers University

Educated at Harvard, Cambridge, and Columbia Universities, Daniel Hausman taught at the University of Maryland, Carnegie Mellon, and for 32 years at the University of Wisconsin-Madison before accepting his current position at the Center for Population-Level Bioethics at Rutgers University. His research addresses methodological, metaphysical, and ethical issues at the boundaries between economics and philosophy, and is currently focused on the ethical appraisal of the use of cost-effectiveness information to allocate health care. The author of nearly 200 books and articles, Hausman also co-founded the journal, *Economics and Philosophy* with Michael McPherson. His most important books are *The Inexact and Separate Science of Economics* (1992), *Causal Asymmetries* (1998), *Preference, Value, Choice, and Welfare* (2012), *Valuing Health: Well-being, Freedom, and Suffering* (2015), and, with Michael McPherson and Debra Satz, *Economic Analysis, Moral Philosophy and Public Policy*. In 2009 Hausman was elected to the American Academy of Arts and Sciences.

2:50 PM: Session II Panel Discussion

These 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?

