INTRODUCTION

As society moves away from a paternalistic view of protecting research participants, many are revisiting the ethics and utility of payment for research participation. The goal of this workshop is to explore the role of paying people for their participation and the impact of payment, as well as the challenges and considerations for how payments should be made. Session 1 will focus on ethical and theoretical considerations. Session 2 will explore the practical challenges and implementations.

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 payment for research participation will:

• Explore the notion of payment for research participation in the context of justice,
• Examine what IRBs and research participants think about payment for participation and the significance of other forms of incentives for participation,
• Describe the financial burdens of participation and possible ways to address them, and
• Identify the logistical and practical considerations for paying research participants.
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<th>Time</th>
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<tr>
<td>10:00 AM – 10:05 AM</td>
<td>Welcome</td>
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<td>10:05 AM – 11:30 AM</td>
<td><strong>Session I: Ethical and Theoretical Considerations</strong>&lt;br&gt;<strong>Moderator:</strong> Neal Dickert, M.D., Ph.D.; Associate Professor, Emory University School of Medicine, Division of Cardiology, Emory University Rollins School of Public Health, Department of Epidemiology, Emory Health Services Research Center, Emory Center for Ethics&lt;br&gt;Advancing Justice, Equity, and Inclusion through Payment for Research Participation&lt;br&gt;Luke Gelinas, Ph.D.; Senior Chair Director, Advarra&lt;br&gt;What Do IRBs and Investigators Think About Payment for Research Participation?&lt;br&gt;Emily A. Largent, J.D., Ph.D., R.N.; Emanuel and Robert Hart Assistant Professor of Medical Ethics, Department of Medical Ethics and Health Policy, University of Pennsylvania Perelman School of Medicine&lt;br&gt;Participants’ Perspectives I:&lt;br&gt;Amie Devlin, Ph.D., M.P.H., M.A.; Epidemiologist, Stratis Group – BluePrint Orphan&lt;br&gt;Participants’ Perspectives II:&lt;br&gt;Alexandra Collins, Ph.D.; Assistant Professor, Brown University School of Public Health&lt;br&gt;Participants’ Perspectives III:&lt;br&gt;Dustin C. Krutsinger, M.D., M.S.; Assistant Professor of Medicine, University of Nebraska Medical Center in Omaha</td>
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<td>11:30 AM – 11:45 AM</td>
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<td>11:45 AM – 12:15 PM</td>
<td><strong>Who Participates in Phase I Clinical Trials and What Are Their Motivations for Participation?</strong>&lt;br&gt;Jill A. Fisher, Ph.D.; Professor of Social Medicine, Center for Bioethics, University of North Carolina at Chapel Hill&lt;br&gt;Are Phase I Clinical Trial Participants Workers and if so, What Rights Should They Have?&lt;br&gt;Roberto Abadie, Ph.D.; Assistant Professor, Department of Anthropology, University of Nebraska-Lincoln</td>
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<td>12:15 PM – 1:00 PM</td>
<td>Panel Discussion&lt;br&gt;Includes Special Guest: Jill Feldman; Lung Cancer Patient and Advocate, Co-founder EGFR Resisters</td>
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<td>1:00 PM – 1:50 PM</td>
<td>Lunch</td>
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**AGENDA**

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| 1:50 PM – 3:15 PM | **Session II: Practical Challenges and Implementations**
                    **Moderator:** Quincy Byrdsong, Ed.D., CIP, CCRP; Vice Provost for Health Affairs, Lipscomb University  
                    **Are Payments All the Same and Should We Always Offer the Same Payment to Participants in the Same Study?**
                    David Borasky, M.P.H.; Vice President, IRB Compliance, WCG IRB  
                    **Addressing the Financial Burden of Clinical Research Participation**
                    Ivy R. Tillman, M.S., CCRC, CIP; Director of Research Operations, Mayo Clinic  
                    **The Logistics of How We Pay People for Research Participation – Equity Considerations**
                    Christine Ritchie, M.D., M.S.P.H.; Professor of Medicine, Harvard Medical School and Director, Mass General Hospital Mongan Institute Center for Aging and Serious Illness  
                    **Paying For Participating in Social-Behavioral Studies – Practical and Ethical Considerations**
                    Celia B. Fisher, Ph.D.; Marie Ward Doty University Chair in Ethics, Professor of Psychology, Director, Center for Ethics Education and the HIV/Drug Abuse Prevention Research Ethics Institute, Fordham University  
                    **It’s Not All about the Benjamins – Other Hurdles Presented by Research Participation, and Why Payment Won’t Resolve Them**
                    C.K. Wang, M.D.; Chief Medical Officer, COTA, Inc.  
| 3:15 PM – 4:00 PM | **Panel Discussion**  
                    **Includes Special Guest:** Jill Feldman; Lung Cancer Patient and Advocate, Co-founder EGFR Resisters |
SPEAKER BIOGRAPHIES

Session I

**Neal Dickert, M.D., Ph.D. (Moderator)**
Associate Professor, Emory University School of Medicine, Division of Cardiology, Emory University Rollins School of Public Health, Department of Epidemiology, Emory Health Services Research Center, Emory Center for Ethics

Neal Dickert is Associate Professor of Medicine in the Division of Cardiology at the Emory University School of Medicine. He holds a secondary appointment in Epidemiology at the Rollins School of Public Health and is a senior faculty fellow at the Emory Center for Ethics. He is Associate Director of the Emory Health Services Research Center and Director of the Georgia Clinical and Translational Science Alliance Recruitment Center. Dr. Dickert is a board-certified cardiologist and Ph.D.-trained ethics researcher.

Dr. Dickert’s research focuses on ethical issues in clinical research and decision-making in clinical cardiology. Specific emphases in research ethics include the conduct of trials in acute care, recruitment and consent for clinical research generally, and the use of incentives and other influences on decision-making. He is an alumnus of the Greenwall Faculty Scholars Program and a past recipient of the Pillars of PRIM&R award. Dr. Dickert is also a member of multiple Data Safety and Monitoring Committees.

**Luke Gelinas, Ph.D.**
Senior Chair Director, Advarra

Luke is a Senior Chair Director at Advarra IRB where he provides analysis and guidance on complex ethical issues arising in the course of clinical research study design and human participant protection. He holds a Ph.D. in Philosophy with a concentration in Ethics from the University of Toronto and an M.A. in Religion, summa cum laude, from Yale Divinity School.

**Emily A. Largent, J.D., Ph.D., R.N.**
Emanuel and Robert Hart Assistant Professor of Medical Ethics, Department of Medical Ethics and Health Policy, University of Pennsylvania Perelman School of Medicine

Emily Largent, J.D., Ph.D., R.N., is the Emanuel and Robert Hart Assistant Professor of Medical Ethics and Health Policy. She holds a secondary appointment at Penn Law, is a Senior Fellow at the Leonard Davis Institute of Health Economics and is affiliated with the Center for Health Incentives and Behavioral Economics. Dr. Largent’s work explores ethical and regulatory aspects of human subjects research and the translation of research findings into care.
Amie Devlin, PH.D., M.P.H., M.A.
Epidemiologist, Stratis Group – BluePrint Orphan

Amie Devlin has an M.P.H. from George Washington University, a Master of Urban Bioethics from Temple University, and a Ph.D. in epidemiology from Drexel University. Dr. Devlin is an Epidemiologist at Stratis Group/BluePrint Orphan currently working with rare diseases and has over ten years’ experience working with IRBs. She has a deep interest in the ethics surrounding financial compensation in medical research. Prior to working as an epidemiologist, she served as Research Program Manager for Temple Health: Block-by-Block (THB3), a research partnership at Lewis Katz School of Medicine which aimed to better understand the health concerns of people living in North Philadelphia. In this role, she conducted qualitative interviews in order to better understand community perspectives on medical research. In addition, her Master’s thesis focused on the ethics surrounding financial compensation in medical research, drawing similarities between medical research participation and other risky professions.

Alexandra Collins, Ph.D.
Assistant Professor, Brown University School of Public Health

Alexandra Collins, Ph.D., is a medical social scientist, investigator and Assistant Professor in the Department of Epidemiology at Brown University’s School of Public Health, and is a member of the People, Place, and Health Collective. Her community-engaged ethnographic and qualitative research focuses broadly on: social, structural, and built environmental influences on risk, harm, and health outcomes among people who use drugs; gender and drug use outcomes; overdose and overdose prevention; implementation and effectiveness of harm reduction interventions; and best practices.

Dustin C. Krutsinger, M.D., M.S.
Assistant Professor of Medicine, University of Nebraska Medical Center in Omaha

Dr. Dustin Krutsinger is an Assistant Professor of Medicine in the Division of Pulmonary, Critical Care & Sleep Medicine at the University of Nebraska Medical Center. He completed his undergraduate and medical degrees at the University of Iowa. He completed his fellowship training in Pulmonary and Critical Care Medicine at the University of Pennsylvania. While at Penn, he completed a Master of Science in Clinical Epidemiology.

Dr. Krutsinger’s research focus is on the efficient and equitable conduct of critical care clinical trials. He is developing and evaluating novel methods to encourage research participation among critically ill patients through both financial and nonfinancial incentives and nudges. Additionally, he is focused on how consent methods and incentives may disproportionately encourage or discourage participation among historically marginalized groups, improving or worsening existing disparities in research participation.
Jill A. Fisher, Ph.D.
Professor of Social Medicine, Center for Bioethics, University of North Carolina at Chapel Hill

Dr. Jill A. Fisher is Professor in the Department of Social Medicine and Center for Bioethics at the University of North Carolina at Chapel Hill. She holds a Ph.D. in Science and Technology Studies, and her research primarily focuses on how clinical trials are conducted and who participates in them as researchers and participants. She has published more than 50 articles and book chapters, and she is the author of “Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials” (Rutgers University Press, 2009) and “Adverse Events: Race, Inequality, and the Testing of New Pharmaceuticals” (New York University Press, 2020). She also edited the collection “Gender and the Science of Difference: Cultural Politics of Contemporary Science and Medicine” (Rutgers University Press, 2011). More information about Dr. Fisher as well as many of her publications can be found at her website: www.jillfisher.net.

Roberto Abadie, Ph.D.
Assistant Professor, Department of Anthropology, University of Nebraska-Lincoln

As a trained medical anthropologist, Dr. Abadie’s research focuses on how different forms of social stratification, in particular, class, race, and ethnicity, contribute to producing and reproducing health inequalities in marginalized populations. His ethnography of professional “guinea pigs” earning a living by participating in Phase I clinical trials in Philadelphia documents the ways in which financial compensation is employed by the pharmaceutical industry to recruit and retain study participants who are exposed to short and long-term risks. Dr. Abadie argues that financial compensation creates a new type of market-captive population whose ability to consent is jeopardized by financial inducements and that to better protect research subjects’ protections and oversight should be enhanced. Dr. Abadie has conducted extensive fieldwork on the ethics of clinical trials, HIV risk, People Who Inject Drugs (PWID), and health disparities among Latino populations in a variety of settings in Latin America, the Caribbean, and the US.

Jill Feldman
Lung Cancer Patient and Advocate, Co-founder EGFR Resisters

I have been a lung cancer advocate for 20 years and then diagnosed myself with the disease in 2009. At the time there was excitement around using a targeted therapy as adjuvant therapy in the post operative setting for people with EGFR mutant lung cancer. There was a trial in NY, but I couldn't participate because I lived in Chicago, had four little kids and the financial burden was too great. I had another opportunity about three years back, but the travel and financial burden was too great, plus I had two kids in college and two in high school.

I also have been advocating for many years and telling researchers to change their mindset and instead of asking why patients are reluctant to participate in trials, ask why aren't we changing the way we develop trials in a way that will allow more patients to participate.
Quincy Byrdsong, Ed.D., CIP, CCRP (Moderator)

Vice Provost for Health Affairs, Lipscomb University

Dr. Quincy J. Byrdsong is the Vice Provost for Health Affairs at Lipscomb University in Nashville, Tennessee. He has operational responsibility for Lipscomb Health to include programs in pharmacy, physician assistant, nursing, dietetics, exercise science, and cardiovascular perfusion. Before coming to Lipscomb, Dr. Byrdsong served as the Associate Vice President for Research Administration at Wellstar Health System in Marietta, Georgia. In this role, Dr. Byrdsong served as the Institutional Official for the Human Research Protections Program (HRPP) and Chief Research Administration Officer.

Dr. Byrdsong received his Bachelor and Master’s Degrees in Biology from Middle Tennessee State University and Doctor of Education degree from Tennessee State University. He speaks to global audiences in the areas of research regulations as well as research ethics. Dr. Byrdsong is a past President of the Society of Clinical Research Associates (SOCRA) and a Member of the Board of Directors for the Association for the Accreditation of Human Research Protections Programs (AAHRPP).

David Borasky, M.P.H.

Vice President, IRB Compliance, WCG IRB

David Borasky, M.P.H. serves as Vice President of IRB Compliance with WCG Clinical. In this position he is responsible for leading quality and compliance efforts for WCG IRB. He has over 25 years of experience managing institutional review boards in a variety of settings including research institutes, global health organizations, academic medical center and independent IRB organizations. He has served as a consultant for the Office of Human Research Protections, the US Department of Energy, the World Health Organization and numerous other institutions. David is a former member of the PRIM&R Board of Directors and in 2018 was named a Distinguished Leader of PRIM&R. He currently serves as Co-Chair of the Subpart A Subcommittee of the HHS Secretary’s Advisory Committee on Human Research Protections.

Ivy R. Tillman, M.S., CCRC, CIP

Director of Research Operations, Mayo Clinic

Ivy Tillman is Director of Research Operations at Mayo Clinic. She earned her Bachelor of Arts degrees in Biology and French from Clemson University, a Master of Science in Health Care Management from Troy University and is currently pursuing her Ed.D in Educational Innovation at Augusta University. Ivy has been involved with human research protections for 17 years and is passionate about research participants’ perspectives and justice in human research.
Christine Ritchie, M.D., M.S.P.H.
Professor of Medicine, Harvard Medical School and Director, Mass General Hospital Mongan Institute Center for Aging and Serious Illness

Christine Ritchie, M.D., M.S.P.H., is Professor of Medicine at Harvard Medical School, the Kenneth L. Minaker Chair in Geriatrics in the Division of Palliative Care and Geriatric Medicine at Massachusetts General Hospital (MGH), and the Director of the Mongan Institute Center for Aging and Serious Illness. She is a board-certified geriatrician, palliative care physician and health services researcher who conducts research focused on optimizing quality of life for those with chronic serious illness, with a particular focus on those living with multiple chronic conditions and those living with dementia, along with their care partners.

Celia B. Fisher, Ph.D.
Marie Ward Doty University Chair in Ethics, Professor of Psychology, Director, Center for Ethics Education and the HIV/Drug Abuse Prevention Research Ethics Institute, Fordham University

Celia B. Fisher, Ph.D. is the Marie Ward Doty University Chair in Ethics, Professor of Psychology and the founding Director of the Fordham University Center for Ethics Education and the NIDA funded HIV and Drug Abuse Prevention Research Ethics Institute. She has chaired numerous ethics committees including for the American Psychological Association, the Society for Research in Child Development, and the American Public Health Association and served as a member of numerous federal and NIH committees including SACHRP, the NIH ABCD and the HEALing Communities studies, and chaired the Environmental Protection Agency's Human Studies Review Board. She is the author of Decoding the Ethics Code: A Practical Guide for Psychologists now in its 5th edition, has over 300 publications and 8 edited volumes on the rights and welfare of racial and sexual and gender minority children and adults and her research has been supported by NIDA, NICHD, NIAID, NIAAA, NIMHD, and NSF. She is a Fellow of the American Association for the Advancement of Science. Her awards include the Lifetime Achievement Award for Excellence in Human Research Protections and the American Psychological Association Award for Outstanding Contributions to Ethics Education.

C.K. Wang, M.D.
Chief Medical Officer, COTA, Inc.

C.K. Wang is a board-certified medical oncologist and the Chief Medical Officer at COTA, Inc. As CMO, he oversees the medical and research functions of COTA and is an expert in cancer care delivery, real-world data/evidence and equity/diversity issues in clinical trial research. Prior to COTA, Dr. Wang held numerous leadership roles at IBM Watson Health and the USMD Cancer Center.