2022 OHRP EXPLORATORY WORKSHOP

BEYOND ALTRUISM — EXPLORING PAYMENT FOR RESEARCH PARTICIPATION

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OASH | Office for Human Research Protections

Program Book

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.

AGENDA

Time	Sessions
10:00 AM – 10:05 AM	**Welcome**
10:05 AM – 11:30 AM	**Session I: Ethical and Theoretical Considerations** **Moderator:** 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*
	Advancing Justice, Equity, and Inclusion through Payment for Research Participation Luke Gelinas, Ph.D.; *Senior Chair Director, Advarra*
	What Do IRBs and Investigators Think About Payment for Research Participation? 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*
	Participants' Perspectives I: Amie Devlin, Ph.D., M.P.H., M.A.; *Epidemiologist, Stratis Group – BluePrint Orphan*
	Participants' Perspectives II: Alexandra Collins, Ph.D.; *Assistant Professor, Brown University School of Public Health*
	Participants' Perspectives III: Dustin C. Krutsinger, M.D., M.S.; *Assistant Professor of Medicine, University of Nebraska Medical Center in Omaha*
11:30 AM – 11:45 AM	**Break**
11:45 AM – 12:15 PM	**Who Participates in Phase I Clinical Trials and What Are Their Motivations for Participation?** Jill A. Fisher, Ph.D.; *Professor of Social Medicine, Center for Bioethics, University of North Carolina at Chapel Hill*
	Are Phase I Clinical Trial Participants Workers and if so, What Rights Should They Have? Roberto Abadie, Ph.D.; *Assistant Professor, Department of Anthropology, University of Nebraska-Lincoln*
12:15 PM – 1:00 PM	**Panel Discussion** **Includes Special Guest:** Jill Feldman; *Lung Cancer Patient and Advocate, Co-founder EGFR Resisters*
1:00 PM – 1:50 PM	**Lunch**

AGENDA

Time	Sessions
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*

Contents

Beyond Altruism – Exploring Payment for Research Participation
OHRP Exploratory Workshop: September 15, 2022

Welcome and Introduction

- Jerry Menikoff, M.D.; Director, Office for Human Research Protections (OHRP)
- Yvonne Lau, MBBS, MBHL, Ph.D.; Director, Division of Education and Development, OHRP

Dr. Menikoff welcomed speakers, moderators, and listeners and thanked them for their participation. He explained that the goals of OHRP's Exploratory Workshops are to provide an open forum for stakeholders in human subject protection, build relationships among them, and explore important topics together.

Dr. Menikoff noted that "undue influence" in regard to payment to participants only exists when the payment threatens rational thinking. Institutional Review Boards (IRBs) are far more worried about this than OHRP is as a regulator. Regulations are not intended to discourage payment, especially not to persons who are economically disadvantaged. Those with fewer resources are no less able to make rational decisions. He hoped participants would explore how payment may contribute to equity, justice, and inclusion.

Dr. Lau also welcomed everyone and expressed her excitement at hosting this annual workshop, especially since this time participants are able to meet together in person again. The workshop will have two sessions. The first will explore ethical and theoretical considerations regarding payment to participants and the second will focus on logistical issues related to payment. She stressed the importance of considerations related to inclusivity and diversity.

Session I: Ethical and Theoretical Considerations

- *Moderator:* 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

Session I Introduction

- Neal Dickert

As the session moderator, Dr. Dickert set the stage by reminding the workshop panelists that the issue of payment to research subjects or participants is not a new issue. It is believed that a fur trapper who had been shot and left with an open wound was the first paid subject. He received $100, then $150 plus room and board while his recovery was observed. Participants in a study of yellow fever were also paid – $100 in gold for participation and a $100 bonus if they were successfully infected with the virus.

Concerns related to payment have been, he observed, "somewhat timeless." They have included the possibility of coercing a subject to participate in a study, undue inducement,

exploitation of vulnerable subjects, and the scientific repercussions of payment. Nevertheless, the discussion of these concerns unfolds differently today than a similar discussion would if held 25 years ago. The nature of those worries has shifted as the context surrounding their consideration has changed. It is widely recognized that offers of money are not really coercive, and discussion about undue inducement and exploitation is beginning to have a different flavor in the wake of rising concern about distributive justice.

He reviewed goals for the first session of the Exploratory Workshop. He hoped speakers, and the discussion following their presentations, would offer contemporary insights into longstanding issues and help the field move past older concerns about coercion and inducement. He anticipated a more sophisticated discussion about the role of different influences on decisions and a discussion of payment that takes into account the modern understanding that there are a number of reasons to participate in research. Speakers will bring a range of empirical data to important conceptual concerns and offer a fresh look at issues related to justice in an era in which diverse representation is emphasized. He also expressed the need for a careful look at the role of context, since payment to participants may raise different issues in the context of different kinds of studies.

Advancing Justice, Equity, and Inclusion through Payment for Research Participation

- Luke Gelinas, Ph.D.; Senior Chair Director, Advarra

Dr. Gelinas sought to map a portion of the conceptual landscape with respect to payment and fairness, raising some questions deserving of further reflection and work in the process. He began by making several important distinctions. He observed that although it seems "a triviality" to note that payment is a benefit for the person who receives it, IRBs do not count it among the benefits of study participation to research participants.

The speaker further noted that payment can be ethically significant in itself or by virtue of its consequences. Both possibilities should be kept in mind. An act that is good in itself can have undesirable consequences. Going to the dentist, however unpleasant, may have good consequences; eating cake may be a good experience that has negative consequences. The same is true of payment to research participants.

One major motivation for offering payment is that it might improve recruitment and retention. It might speed enrollment and study completion, prevent under-powered studies, and make early termination less likely. This would make it "instrumentally good." However, it could also have neutral or even negative effects:

- In some contexts, it might *not* significantly improve recruitment or retention;
- It might compromise the validity of informed consent (undue influence);
- It might have wider, arguably negative unintended effects, such as motivating serial participation, encouraging a Phase 1 healthy volunteer-worker class, or motivating dubious behaviors on the part of participants (e.g., deception).

If any of these occur, payment would be *instrumentally neutral* or *bad.* The actual consequences in the real world are not always known in advance. They need to be studied with

rigorous empirical methods. Offering payment (or certain payment amounts) could result in over-representation of certain groups (e.g., those who are economically vulnerable), but it also could correct for under-representation of some groups. By influencing the composition of study samples, payment can influence the distribution of research risks and benefits, both short- and long-term, across societal groups. This is a matter of *distributive justice* or fairness.

To better assess the possible consequences of payment, it is important to consider: *What are the effects of payment (or different payment schemes) on the demographic composition of study samples? What are the variables related to ethics or fairness that should be measured?*

Regarding reimbursement for out-of-pocket expenses and compensation for time and opportunity costs, Dr. Gelinas felt that payment was a fitting and fair way to restore participants' financial resources (reimbursement) and acknowledge their time and sacrifices (compensation).

Speaking of payment in terms of fairness urges us to consider its relation to another important ethical concept, that of "exploitation." *Exploitation* occurs when one party takes unfair advantage of another (Wertheimer, 1999). Unfair advantage occurs when there is a significant misbalance of costs and benefits between parties. Research could be exploitative of participants when researchers benefit but participants are left significantly worse off. It is an open question how much real-world research fits this description. The speaker stressed that focusing on informed consent will not necessarily mitigate or prevent exploitation. Instead, the speaker advised, consider increasing benefits to ensure a fair balance of costs and benefits. Payment is one way to accomplish this (Largent, 2017).

This leads to the second question proposed by the speaker: *Is providing payment to participants the best way to address concerns about research exploitation?*

In the remainder of the presentation, Dr. Gelinas focused on the moral status of payment to participants and whether it might be considered obligatory. Dr. Gelinas observed that fairness is typically thought of in deontic terms (right or wrong). If paying is fair, would failure to pay be unfair? And isn't what's unfair usually *wrong*? This analysis, if accepted, would have significant implications for the clinical research *status quo.*

Dr. Gelinas ended the presentation with an under-explored argument for the idea that paying participants is obligatory, or at least strongly supported by ethical reasons. The opportunity to participate in research is itself a good. Everyone should have a fair/equal opportunity to access or realize this good. Also, research is a social activity that generates *social goods* in which everyone should be able to share. Many people do not have a fair or equal opportunity to access research because of financial obstacles to participation. If these obstacles can be removed by paying participants, there is strong reason to do so.

Is there strong reason to ensure that everyone has fair/equal access to research? Or, further, is there a ***right*** *of fair or equal access, one that could ground corresponding obligations to facilitate access?* Dr. Gelinas felt there were often strong grounds for offering payment and thoughtful payment schemes. However, it is not possible to be confident about the ultimate

moral status of payment without getting relatively clear on its consequences in different domains.

What do IRBs and Investigators Think about Payment for Research Participation?

- 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

Dr. Largent shared research findings about how IRBs and investigators think about research participation. Specifically, she explored findings related to coercion and undue influence, exploitation, advertising payment, payment-induced deception, completion bonuses, the Federal Anti-Kickback Statute, taxation, and eligibility for benefits.

Coercion and undue inducement. The Common Rule provides that "an investigator shall seek informed consent only under circumstances that … minimize the possibility of coercion or undue influence."

Empirical evidence shows many IRB members and investigators are confused about how to define these terms, which can lead to a conservative approach to payment of participants ("better safe than sorry!") (Largent, Grady, Miller, and Wertheimer, 2012 and 2017; Largent and Lynch, 2017). To understand when, if ever, payment would cross the threshold such that it was coercive or unduly influential, it is important to clarify what these terms actually mean. Clearer definitions should reduce worries about coercion and undue influence.

Exploitation. There is some concern that offers of payment will preferentially encourage enrollment among people of lower socioeconomic status (i.e., unjust inducement), thereby exploiting unjust background conditions. This may lead some IRBs or investigators, paternalistically, to pay less. (Persad, Lynch, and Largent, 2019). However, there is no compelling evidence that unjust inducement is a problem in later-stage research. Participants also may be exploited if they receive inadequate payment for their contributions to research, which is an argument for paying more.

Advertising payment. Recruitment is the start of the consent process, and recruitment materials are subject to IRB review. OHRP tells IRBs to "carefully review the information to be disclosed … to ensure that the incentives and how they will be provided are clearly described." IRBs' policies on advertising payment vary widely. For example, some prohibit any mention of payment, some don't allow a specific dollar amount, and some actually do require a dollar amount. (Gelinas, Lynch, Largent, Shachar, Cohen, & Bierer, 2018; Largent & Lynch, 2017). How will payment work as recruitment tool, Dr. Largent asked, if people don't know it is offered?

Payment-induced deception. Some IRB members and investigators worry that offering payment may cause some participants to lie or mislead researchers (e.g., about their eligibility to participate or their experience of adverse events or side-effects). Participants who engage in such deception may expose themselves to risks or undermine the scientific integrity of research. A recent survey experiment explored whether offers of payment will induce participants to

deceive about their eligibility and, if so, whether higher payments lead to more deception. To date, there is no evidence that higher payment causes increased rates of deception. The investigators found that offering payment did encourage some participants to lie about their eligibility for the survey but paying more did not result in more lying (Lynch et al, 2019). It would be helpful to study the phenomenon of payment-induced deception in biomedical research.

Completion bonuses. Completion bonuses – payment that participants can receive only if they finish the study or reach a pre-specified endpoint – remain ethically controversial due to concern that such payments will coerce or unduly influence participants not to exercise their right to withdraw. Although they aren't coercive, there may be concerns about undue influence. Dr. Largent suggested that completion bonuses can be acceptable within appropriate guardrails, which might include:

- Pay completion bonuses to any participant who reaches a point at which further participation would be objectively unreasonable.
- Differentiate reimbursement and compensation from completion bonuses and pay reimbursement and compensation out over the course of the study.
- Clarify the terms under which the completion bonus becomes an entitlement.
- Restrict the bonus amount so that it is not so disproportionate to the amount of money a participant might make outside the study (or in the course of the study) (Largent & Lynch, 2019).

Federal Anti-Kickback Statute. The Federal Anti-Kickback Statute (AKS) makes it a criminal offense for any person to knowingly and willfully offer, solicit, or receive remuneration to induce the utilization of services paid for by federal health care programs. Some IRBs worry that payments to participants may violate the AKS. After reading many advisory letters written by the HHS Office of the Inspector General, Dr. Largent concluded that remuneration is likely to be acceptable if it helps accomplish the needs of the study – typically, the recruitment and retention of participants – and advances the scientific validity of the study. She advises researchers to offer payment under conditions that limit the risk of overutilization of a federal health benefit program. Any clinical care billed to such a program should be dictated by a well-developed trial protocol (Largent, Heffernan, Joffe, & Lynch, 2020).

Taxation and eligibility for benefits. Dr. Largent stressed that payments to U.S. participants are taxable income and must be reported as such. As a result, payments could affect participants' eligibility for benefits programs such as Supplemental Security Income (SSI). This possibility should be noted in consent forms, as this could affect one's willingness to participate in research. Requiring participants to provide a social security number, which may be needed for tax purposes, could also have an adverse effect on representativeness.

Participants' Perspectives I

- Anne Devlin, Ph.D., M.P.H., M.A; Epidemiologist, Stratis Group – BluePrint Orphan

Dr. Devin focused on the findings of a study that asked open-ended questions of North Philadelphia residents in 58 semi-structured interviews (Fisher & Devlin, 2019). The study's goals were to examine community perceptions of financially compensating research participants and explore the ethics of providing financial compensation. She noted that Principal Investigators (PIs) often reach out to IRBs and ask for guidance on payment, and she felt it was important to know how participants saw the issue. While interview questions focused on research and did not specifically address compensation, half the interviewees brought up issues related to payment to participants.

Emerging themes showed that participants appreciated reimbursement for their time and energy and recognized the importance of financial benefits. However, some expressed concern about risk and the intentional targeting of low-income or desperate participants. Participants pointed out that people who engage in research for financial reasons may not care about giving truthful input, and this could affect study validity.

Some participants stressed the importance of compensation, referencing the financial resources of sponsors such as drug companies. Others noted that other members of study teams are compensated; they felt that participants, too, deserved compensation for sacrifices such as having to take time off work for travel.

For some, the financial benefits of study participation were significant. For example, one person said that the financial benefits of her husband's participation in a study after he lost his job saved their house.

Some participants, observing ads posted in health clinics and on public transportation, said this placement made it clear that certain studies target "desperate, poor people." Some advised that such desperate people would focus solely on the money: **"**Oh, we can just go ahead and give 'em any old kind of answers." Another observed, "Only people that care about science is scientists."

Some expressed concern for desperate participants: "If you going to jeopardize your body and your life just to get a couple hundred dollars … I think that's foolish. You have to be committed within yourself ... and not just think about the money…." Participants stressed that compensation "can definitely be a lure."

Participants' Perspectives II

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

Dr. Collins also focused her remarks on how structurally vulnerable populations perceive compensation for research participation. She held that debates about compensation for such populations are often rooted in stigmatizing notions of capability and capacity. Such attitudes

and resulting approaches to compensation may obscure details about the research context and risk excluding participants who might benefit from the research. They also may reduce the agency of structurally vulnerable populations participating in research.

How do structurally vulnerable populations conceptualize their research involvement and what shapes their willingness to participate? Collins participated in a study that explored the following specific questions (Collins, Strike, Guta, Turje, McDougall, Parashar, & McNeil, 2017):

1. What is equitable and fair compensation?
2. How do social constructions of vulnerability impact approaches to compensation and protection of participants?
3. How do participants conceptualize research involvement and how does this differ from how IRBs see it?
4. What impact do power dynamics in research have on participation and how can these be upended?

The disparity in knowledge and power dynamics present within research were readily cited as creating "unfair" interactions. Study participants felt researchers did not acknowledge their structural vulnerabilities and daily experiences when conducting research. The researchers seemed to operate outside the participants' own social and structural contexts. Participants wanted the realities of their lives acknowledged. They felt researchers simply extracted data from them and then never communicated their findings, despite the potential benefits of doing so.

Study participants challenged the one-sided nature of research as researchers seemed to perceive it and reframed it as transactional: researchers need data, participants have the expertise to meet that need. They wanted to leverage power to ensure fair payment for meeting that need: "I can give you the data you want if conditions are right."

For people with structural vulnerabilities, study participation often hinges on compensation. For these participants, research was viewed as a legitimate way of making money that could supplement other income and was understood to be work. Participants provide a service that should be compensated. Research takes time and competes with people's efforts to survive, so compensation needs to be respectful of these realities.

Compensation approaches held a deeper significance in terms of how participants felt they were perceived by researchers. Participants alluded to the ethical concerns undergirding institutional compensation practices. Lack of payment was unacceptable ("I won't work for you for no pay"). Gift cards were generally seen as paternalistic, stigmatizing, and inadequate. Cash was seen as a fairer form of compensation. Participants acknowledged that researchers work within a budget but stressed that fair compensation was imperative for participation.

Dr. Collins suggested the following four takeaways from study findings:

1. Research can be a form of work among structurally vulnerable populations and

deserves equitable compensation.
2. Non-cash compensation is paternalistic and can reinforce structural vulnerabilities by restricting agency.
3. There is a need to rethink how certain populations are perceived within the biomedical system (experts vs. volunteers).
4. Compensation restrictions should not vary between IRB-deemed "vulnerable" and non-vulnerable populations.

In light of these findings, she proposed the following next steps:

- Ongoing relations of power and privilege must be critically interrogated within health research apparatuses.
- The complexities shaping research participation must be acknowledged. We need approaches that are ethical but not one-size-fits-all.
- The perspectives of those labeled by IRBs as "vulnerable" need to be prioritized when determining compensation approaches, and there should be transparency in these decisions. It is important to listen to prospective participants and make space for their perspectives. The speaker also advised involving them in decision making as research is planned.
- There is an urgent need to move past paternalistic assumptions of risk and acknowledge that respect for persons is more complex. The idea that certain populations need more supervision and control than others is very harmful.

Participants' Perspectives III

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

Dr. Krutsinger focused his remarks on findings related to undue and unjust inducements. He stressed that there are genuine concerns with payment:

1. Payment may be an **undue** inducement. In the face of financial compensation, a subject's sensitivity to risks may be blunted.
2. Payment may be an **unjust** inducement to participate for people who have received less social benefits.

A 2004 study tracked income and demographics of participants who were offered varying amounts of compensation ($100, $1000, or $2000) to participate in theoretical studies that posed different degrees of risk (Halpern, Karlawish, Casarett, Berlin, & Asch). Researchers found that as the risk increased, the willingness to participate went down regardless of amount of amount paid. Participants were making a rational decision in which risk and financial compensation were balanced. However, there was no evidence of undue or unjust inducement in the study.

In another study that explored the possibility of unjust inducement (Halpern et al., 2021) participants were offered either no money, $200, or $500. In a smoking trial, the consent rate increased with increases in the rate of payment. However, in an ambulation trial, these

increases had little impact. Researchers theorized that the ambulation study was seen as beneficial and had high consent rates even without payment.

A 2010 study (Cryder et al.) explored study payment as a signal of risk. Prospective participants were offered different theoretical amounts of payment ($25 to $1000). They thought the study "must be risky" when higher amounts were offered. Also, when higher amounts were offered, participants viewed enrollment materials longer, reflecting increased concern.

Unpublished data from the RETAIN trial suggests that incentives may help improve diversity in enrollment. However, these data need to be replicated.

In conclusion, the speaker noted:

1. Incentives work for some trials but not all trials.
2. Data on undue and unjust inducement are reassuring so far, but need further evaluation in more trials with higher risk.
3. With ethical concerns not yet manifesting, and real benefits to compensation, it may be time to shift the burden of proof to those who would bar incentives.

Who Participates in Phase I Clinical Trials and What are Their Motivations for Participation?

- Jill A. Fisher, Ph.D.; Professor of Social Medicine, Center for Bioethics, University of North Carolina at Chapel Hill

Dr. Fisher stressed that volunteers play a critical role in all phases of drug development (healthy volunteers in Phase I trials and affected patients in Phase II and II trials). Phase I trials are safety studies, and they may be designed to investigate the ability of humans to tolerate an investigational drug at various doses. Other types of healthy volunteer trials may focus on metabolism, drug interaction, or bioequivalence (the generic market).

Phase I trials normally require healthy volunteers to be confined for some portion of the trial. The confinement can last days or weeks, and healthy volunteers typically receive compensation of $200 to $250 per day. Clinics often prefer to enroll repeat participants because these subjects know how the trials work and can be trusted to complete the studies. Most healthy volunteers have participated in prior clinical trials. Most participants are male, and a disproportionate number are members of minority groups. Most are between 20 and 45 years old. The majority have relatively low income and educational attainment, with unstable employment histories. Many have a history of incarceration, and many are immigrants (some of whom are not legally permitted to work in the US. (Fisher, 2020). Given these data, Dr. Fisher posed the question: "Why doesn't the higher percentage of racial and ethnic minorities in Phase I trials feel like a recruitment success?"

Minorities participate in the riskiest studies with no direct medical benefit. Dr. Fisher argued that racial and economic inequalities in the US create a market of healthy volunteers for Phase I trials. She also flagged concerns about validity that arise in Phase I drug testing but noted that

these concerns were outside of the scope of the day's agenda.

The speaker observed that Phase I participants are typically motivated to enroll by financial considerations. One subject said, "I don't want to save the world. No, I need to make money." A financially desperate subject explained, "Where else am I gonna get it [income]? Car's broke down, you know. What are we gonna do? If I don't pay my parole I'm gonna go back to prison." For some participants, their situations remain precarious as they continue to rely on trial participation for income, sometimes for years. She noted that the vast majority of trials pay less than $4000. In general, participants tended to screen for 3 trials, participate in 1-2 trials, and earn roughly $4,000 annually. While some initially thought that the compensation from trial participation might change their lives, at best it helps make ends meet temporarily.

In closing, Dr. Fisher noted that social and economic inequalities in the US help funnel people of color into Phase I trials because many from low-income groups do not have better options to earn income. Though the compensation may appear substantial, it does not provide financial security. The ethical problem is not necessarily that participants' decision-making is distorted for any single trial by the offer of compensation, but by the false expectation that by continuing to enroll in more and more trials, they can permanently transform their lives and provide financial freedom.

Are Phase I Clinical Trial Participants Workers and if so, What Rights Should They Have?

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

Dr. Abadie lived among a community of professional study subjects living with HIV for 18 months in order to document their preparations for the trials, their decision-making processes, and their everyday lives. He wanted to understand their motivations for study participation, assess how much they knew or cared about long-term and short-term risks associated with these studies, and determine how financial gain influenced their decision to participate.

He found that they saw themselves as "contractors" within the gig economy. One described the experience as "letting people pay me in exchange for the control they have over me," or, as another put it, "for being bored to death." For professional participants, financial constraints typically make informed consent a meaningless formality: "You are free to consent but it's a very coercive thing because they know you need the money." Payment, the speaker noted, does not buy trust.

Dr. Abadie suggested that a social justice approach to the prevalence of professional "guinea pigs" would be to provide better working conditions, higher pay, and a limit on the number of trials. Besides possible risks to repeat participants, in some instances there could be issues with trial validity. While there is currently no centralized registry that could help monitor and control trial participation, in 2006 European pharmaceutical companies did implement such a registry.

A community-based organization called "Act Up," funded by AIDS activists, provides an alternative model to paid participation. It was a partnership among clinicians, patient advocates,

activists, and patients. Most participants were poor African Americans and Latinos undergoing care and enrolled in HIV trials. They did not receive financial compensation other than train tokens or parking. Rather, their enrollment was a strategy to help them fight for their lives and learn about disease management. In contrast to the damaging power relationships with researchers that Dr. Abadie believes are common in trials with paid subjects, these participants trusted their doctors and felt they were participating in a true partnership.

Dr. Abadie favored an alliance among engaged physicians, patients, and communities to bridge the equity gap in clinical trial participation. He advised moving from an emphasis on either financial payment or pure altruism towards a collective effort to address structural and individual barriers to inclusion in clinical trials research. Some trials could offer payment while others might move beyond it. While such an alliance may not be created successfully for every trial, it has been done in studies with those affected by HIV and can be replicated. The "astroturf" organizations funded by the pharmaceutical injury to nudge doctors to prescribe off-label medications are definitely not the type of alliance Dr. Abadie is suggesting. Rather, the partnership must be community based and reflect a genuine alliance of interests. Such an effort can increase minority participation in needed research.

Panel Discussion I

- Includes special guest Jill Feldman; Lung Cancer Patient and Advocate, Co-founder of EGFR Resisters

At the moderator's invitation, Ms. Feldman reflected that the patient community probably does not know how much interest there is in this topic. She expressed appreciation for including patients in the conversation and thought presentations were "fantastic." She noted that a persistent difficulty is ambiguity around definitions – for example, reimbursement, incentives, and compensation. These mean different things to different people in different situations.

She stressed that people should not have to pay to participate in trials, but many do pay for parking, transportation, child care, and the need to take time off work. Out-of-pocket expenses can be significant. At the same time, for many participants, lack of payment does not prevent enrollment. A friend with cancer who participated in six clinical trials told her that "undue influence is crap." She was induced to participate solely by "my impending mortality."

Ms. Feldman noted that researchers often talk about patients as part of a team, but patients are the only team members who are not compensated. Researchers are rewarded by opportunities to publish and present their findings and industry sponsors get valuable data. If the research enterprise is serious about participants as team members, it is logical for participants to expect compensation.

Ms. Feldman endorsed the concept of including communities and patients in conversations about research, which would help promote trust. Patients' lives are complicated. Clinical trials are a snapshot within their lives, in which they must make decisions, manage side effects, continue to work, find pleasure, take care of family, and make future plans. What are patients giving up when they agree to be participants? How can you help them participate?

Respect and trust. Responding to these remarks, Dr. Dickert noted that respect for participants is shown not only through the informed consent process but also through all the research team's interactions with patients. He added that payment may have some value as a sign of respect. He invited comments on issues related to payment and trust. Ms. Feldman observed that the discussion of reimbursement frequently does not emerge prior to the informed consent process and should occur up front. There are times, however, when access to providers is so important that the payment does not really matter.

Dr. Byrdsong stressed the importance of recognizing what is motivating people to participate and interacting with them in ways that show you, as researcher, understand and care about those motivations. If interactions show the researcher is thinking about what is best for that individual, given that person's reasons for participating, then trust can be built. The researcher's motivations are also important. Is the researcher offering money to get the individual to enroll or out of gratitude and a sense of fairness?

Dr. Devlin observed that there are multiple layers to the issue of trust. One level is the relationship between the individual researcher and the subject, while another is the relationship between the individual and the research enterprise as a whole. Relationships formed with organizations and institutions also have ripple effects in trust building. Trust happens in many ways.

Ms. Tillman saw trust as closely linked to transparency. Informed consent documents packed with legal language diminish trust. She noted that patients remember and appreciate clear and transparent conversations with researchers about who is going to pay for what as the trial progresses.

Ms. Feldman added that she did not participate in two trials because of travel and related costs. She would gladly volunteer her blood and tissue wherever it might help, but she has four children and can't always do this. She stressed the importance of an easy-to-read informed consent summary to promote transparency. Both literacy and numeracy are issues. More people would participate in trials if more effort were put into graphics and clear communication throughout the informed consent process. There also should be a way to contact researchers with questions.

She further observed that trust goes beyond a single trial. Often, when a trial ends, there is no process for continuing care and the subject feels abandoned. This experience necessarily diminishes trust.

Dr. Wang added that recent research confirms both the importance of readable consent forms and after-trial planning in building and sustaining trust with participants. Dr. Dickert reflected that the discussion suggests that trust is built or harmed within the larger context of interactions with the participants, of which payment is a part.

Payment and deception. Observing that several speakers mentioned concerns that participants might deceive investigators because of their desire for payment, Dr. Devlin invited speakers to "flesh out" this topic. She thought this concern was more likely to arise in some contexts and

not in others.

Dr. J. Fisher commented that it is important to bear in mind that not all studies are equally trustworthy. Even when healthy volunteers believe in the research enterprise as a whole, their awareness of the commercial interests behind a study may affect their level of trust. Factors such as IRB oversight and payment may help offset concerns. Rule breaking does happen, and this may occur for a variety of reasons. Participants may not understand why a rule is important, or they may simply be bored (for example, exercising when this is forbidden by the rules). More attention to their welfare might result in greater compliance. At the same time, it is important to remember that pharmaceutical companies sometimes break the rules for financial gain.

Dr. Largent suggested that more attention is paid to whether people will tell the truth than is really warranted. There are studies of healthy participants that suggest most people do tell the truth, even when financial incentives are offered that might encourage them to lie. There are non-payment related solutions to the problem that should be considered, including educating people about why honesty is important for safety and scientific rigor. In response, Dr. Dickert observed that we probably know more about payment and deception in studies with healthy volunteers than we do in other contexts and that this is likely a concern that is isolated to specific kinds of research. He suspected that in late-phase trials, for example, this is not a concern, because people are generally seeking entry into these trials based on health-related motives.

Ms. Feldman again stressed the importance of educating individuals, families, and communities about the purpose of the study, how data will be used, and how it may help others. Transparency is key. It is also important to share study results and provide periodic updates.

Payment and diversity. Dr. Dickert highlighted the potential role of payment in increasing the diversity of participants. Observing that low-income populations may be suspicious of efforts to target them specifically, he invited perspectives on the role money can and should play in addressing this goal.

Dr. Largent stressed the importance of compensating participants for all the ways in which study participation may affect them.

For some studies, Dr. J. Fisher observed, we do want to know more about marginalized populations and the study is specifically designed to recruit them. In such cases, it is appropriate to sample from those populations. Studies that seek general information may lack validity if they do not have an appropriate distribution of the population from an economic perspective. Perhaps, she suggested, such distribution should even be a requirement.

Dr. Krutsinger wondered when economically disadvantaged populations sense that they are being targeted. If a general study offered compensation to everyone, would they still sense that they are being targeted and perhaps taken advantage of?

Dr. Byrdsong cautioned that people should be careful about their assumptions when they seek

minority participation. A minority population is not necessarily all poor, and a white population is not all well off. It is important not to conflate issues. Payment will help to increase enrollment for poor people whether or not they are members of an ethnic or racial minority. If the goal is to improve access to trials for people with lower economic status, then the outreach mechanisms chosen need to help accomplish this. Strategies such as putting notices about studies on buses are entirely appropriate. Ms. Tillman added that providing opportunities for people with lower economic status to participate on Community Advisory Boards (CABs) is also helpful.

Payment size and structure. Dr. Dickert said that simply having the humility to ask questions about payment and being willing to learn is extremely important. He then invited Dr. Krutsinger to comment on the issue of how appropriate amounts and structures for payment should be determined.

Dr. Krutsinger stressed that the amount of payment should be tailored to the specific population, the risks posed by the study, and other variables in the study setting. For large studies, it is advisable to do some pilot testing to see what amount of payment would help move the needle on the decision to participate and what amount communicates appropriate respect for the value of participation. Dr. Dickert observed that increasing amounts of money could make people skeptical and, in theory, might even lower enrollment.

People are the experts concerning their own lived experience, Ms. Feldman observed. It is essential to involve community members in identifying barriers to participation and calling attention to what people would have to give up to participate. Many people can't take off work unless they receive what they would get paid for a day's work.

In closing, Dr. Dickert noted that it is only recently that the field began collecting data on this subject. "We should have been asking patients about this issue a long long time ago."

Session II: Practical Challenges and Implementations

- *Moderator:* Quincy Byrdsong, Ed.D., CIP, CCRP; Vice Provost for Health Affairs, Lipscomb University

Session II Introduction

- Quincy Byrdsong

Dr. Byrdsong explained that Session II will shift the conversation from theoretical to practical considerations related to payment of participants. Session I explored topics such as why we pay participants, how we make sure payments are equitable and just, how we align payment with research objectives, why we pay staff but not participants, and whether it is right to target specific populations for payment. It also explored ethical issues such as how risks and payment are weighed and stressed the importance of dialogue with participants to better understand how payment influences decision-making. Session II will envision *how* payments should be made with different study populations in different settings.

Are Payments All the Same and Should we Always Offer the Same Payment to Participants in the Same Study?

- Dave Borasky, M.P.H.; Vice Present, IRB Compliance, WCG IRB

Mr. Borasky noted that for many years issues related to payment of trial participants have caused discomfort. The same questions are being asked today that were asked 25 years ago. Regulations and guidance provide no clear answers, and IRB decisions are generally quite subjective.

In addressing this persistent issue, Mr. Borasky said it was important to remember that payments to participants are not all the same. In fact, they are quite nuanced and different. Participants' reasons for participation are not the same and all studies are not the same, so why would we think of decisions about paying participants as the same in all cases? The research context has many facets that are crucial to bear in mind as payment is considered.

There are many reasons researchers might offer participants money. These include:

- Reimbursement for costs incurred due to participation (for example, parking);
- Compensation for time, effort, and inconvenience;
- Tokens of appreciation, such as a gift card;
- Incentives to participate in research (the reason that is most likely to cause concern for IRBs and ethicists);
- Financial incentives designed to influence behavior in experimental intervention trials (for example, to encourage adherence to a smoking cessation program).

Participants have many different reasons for participating in research. These include:

- *Altruism and/or a personal interest in science.* Some participants just wish to see science advance and may even refuse payment.
- *Access to new therapies.* A common reason for participating is that participants are seeking a cure for their own disease or condition and have not responded to other available treatments.
- *Financial incentives that are not direct payment*. An example is that a study might offer access to care at reduced cost.
- *Source of income*. There is an active network of profession participants who do studies as a source of income. For example, Mr. Borasky participated in studies as a source of summer income while he was in college.

Factors to consider include the type of research (for example, Phase I First in Human, Phase I oncology, Phase III placebo-controlled randomized controlled trial [RCTs], pragmatic trials, or open label trials) and the burdens of participation in the particular trial in question. In assessing burdens, factors to consider include the impact of geographical differences; out-of-pocket costs (such as hotels and travel expenses); the number of clinic visits; interference with commitments such as employment, school, and childcare; and the burden of forgoing standard-of-care treatments to accept a randomized alternative.

Should we always offer the same amount? Mr. Borasky answered, "probably not." Circumstances vary, and costs and burdens not same for all participants. Demographic targets may require a diversity of sites and different incentives to attract the desired populations. Admittedly, the issue of fairness arises when participants at a single site are offered different payment amounts. Some studies offer payment on sliding scale, but from a practical standpoint it may be difficult to have people accept that. Who decides where people should fall on the scale?

In closing, Mr. Borasky stressed that context continues to be a factor when payment is considered. Already, RCTs are using different approaches to payment that reflect their context. He noted that offering variable incentives within a site would be complicated. A variable payments model that mitigates real and perceived concerns continues to be elusive.

Addressing the Financial Burden of Clinical Research Participation

- Ivy R. Tillman, M.S., CCRC, CIP; Director of Research Operations, Mayo Clinic

Ms. Tillman focused her remarks on how payment issues look different when we change our lens to explore them from participants' perspectives. She explained how this is different:

- *Organization-focused*: From this perspective, researchers are conveyers of knowledge and as such maintain asymmetrical power relations with the community. The assessment of burdens associated with clinical trial participation is made from a distance.

- *Participant-centered*: Looking through this lens, the voices of participants are valued and researchers are able to appreciate the diversity of participants, their experiences, and their burdens. Peer-model assessment allows researchers to appreciate the burdens associated with clinical trial participation as participants see them.

Participant-centered assessment (Cameron et al., 2020) reveals burdens related to the family, the implications of time away from family, the family's perception of the participant's burden, changes to the role of the participant as provider and caregiver, the implications for study participation for the participant's caregiver and partner, a wide range of responsibilities and obligations to take into account, and the need to care for side effects. These burdens are not all related to finances. For example, helping a family member deal with side effects is not a burden that can be addressed by writing a check.

The weight of these social burdens of participation may differ depending on the study location (for example, rural vs. urban), medical insurance status, the disease or condition, participants' socioeconomic status, citizenship status, and payment timing and amount. Researchers should also consider what happens to participants when the study is over. Some participants feel "dropped" after protocols through which they received care. Will they have access to post-trial investigational and commercially available treatment or help managing long-term side effects? When the product is available, can they afford to get it? When findings are identified, do they benefit?

Ms. Tillman stressed the importance of educating communities about clinical trial participation and hearing their concerns. The Human Research Protection Program (HRPP), the IRB, researchers, and the community all need to play roles in bringing issues forward. For example, some individuals may not want to give their social security number for a range of reasons, and methods of payment will need to be considered with this in mind. She encouraged HRPPs to leverage existing structures such as Patient Advisory Boards, which can provide useful feedback. Once built, community partnerships should be sustained to increase transparency.

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, Massachusetts General Hospital, Mongan Institute Center for Aging and Serious Illness

Dr. Ritchie began with a review of four models for compensating research participants:

- *The market model:* This model stresses payment as a way to induce participation. It commercializes studies and addresses competition for potential participants.
- *The wage model:* Study participation is viewed as an unskilled "job."
- *The reimbursement model:* This approach addresses participants' expenses, including compensation for loss of employment and caregiving requirements. This approach is costly and can perpetuate disparities.
- *The appreciation model:* Participants are given tokens of gratitude such as gift cards. These may not take into account intangible costs of participation.

Research participants may be compensated with cash, gift cards, or perks such as lunch and "swag." The Internal Revenue Service (IRS) has ruled that such compensation is taxable if it exceeds $600/year, which means that if the study team is not tracking compensation by social security number it may not be aware that the compensation of participants who are in other studies has exceeded this amount. Approaches to comply with this IRS ruling l~~egislation~~ may look very different in different locations and different institutions. Disparities that can inadvertently occur as a result of this legislation include risk for higher taxes and the possible loss of eligibility for federal benefits. Personal information provided to facilitate payment may also be at risk through breaches in confidentiality.

An additional concern related to the current approach to compensation is that it does not factor in the societal benefits of participants' participation. Sometimes participants do not even receive reimbursement for the overall costs they incur as a result of participation (such as transportation, loss wages, childcare, parking, etc.). Lack of transparency or consistency in approaches to compensation may erode trust in the research enterprise. The current compensation rules go against the principles of community-engaged research/person-centered design, which seek to honor the value of persons and communities in the research enterprise and to optimize equity and representativeness. Another way to think of research participation is as a public good from which everyone in society benefits. If as a society, we thought of research participation accruing to overall community benefit, our policies would reflect more respect for the activity. Like charitable giving, it would result in some credit for doing needed work.

Dr. Ritchie highlighted several potential solutions to current dilemmas related to participant payment. These include:

- Specific and empirically informed payment guidance and transparency. This would mean that for certain types of studies with certain levels of participation or risk, a clear range of reimbursement would be expected. These ranges of reimbursement might take into account regional cost-of-living indices and other factors. For example, institutions and federal agencies often publish specific per diem rates for travel to specific geographical regions. NIH and other agencies could offer a similar guidance for reimbursement.
- Removing W-9/SSN requirements and replacing them with requirements for participation in a research registry. If research participation is seen as a public good, then the emphasis would be less on income from participation and more on prevention from harm by participation in research studies that negatively interact with each other. A research registry (mandated in some countries) could mitigate harm.
- Recognizing research participation as a charitable contribution that is rewarded with a tax exemption or credit.
- Social recognition of the important contributions to science made by research participants.
- Better communication with participants about the outcomes of the trials in which they participate.

Paying for Participating in Social-Behavioral Studies – Practical and Ethical Considerations

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

In social-behavioral non-intervention studies involving economically marginalized populations, researchers, IRBs, and CABs can determine a fair and equitable payment amount. However, ethical dilemmas still arise from the interface between such payments and participants' lived experience. Are payments just or unjust if the researcher knows that:

- Participants would prefer not to participate, but do so because they need money or are pressured by outside sources?
- Populations are recruited because they engage in health-comprising behaviors and tell the investigator they will use the payment to engage in these behaviors?
- Community researchers will bear the burden of payment-related threats to scientific validity and moral harms?

Dr. Fisher reported on three studies that explore "ethics beyond the dollar" in working with specific vulnerable populations.

Female Sex Workers (FSWs). FSWs in under-resourced countries are at high risk for HIV and

other sexually transmitted infections (STIs). They are a difficult to reach and socially stigmatized population. Research on individual and systemic factors is critical to promote health equity by informing public health policies. This study reported on post-study interviews to determine how FSWs in India perceived payments for their participation in research (Reed, Fisher, Blankenship, Brook & Khoshnood, 2016).

Is understanding the right to withdraw enough? Respondents expressed concerns about withdrawal, even though they understood they had the right to do so. Many were living in dire conditions and needed the money to survive. One expressed the concern that if she withdrew, she might not have the opportunity to participate in additional studies. Others voiced the opinion that discontinuing participation would be disrespectful.

Community coercion also surfaced as an issue. One said that brothel managers took a portion of her payment for participation and another had to give a commission to another FSW for the opportunity to enroll. Given concerns like these, Dr. Fisher questioned whether fair payment alone is ethically sufficient.

She noted that SACHRP has distinguished between coercion and inducement (HHS SACHRP, 2019). SACHRP defined coercion as investigators' threat to someone's rights, or withholding of money to obtain compliance. Inducement, on the other hand, is a genuine offer of payment for research participation. She questions whether fairly priced inducements or compensation should be offered under circumstances like the following:

- The amount itself is not coercive, but leads to coercion by community gatekeepers;
- Not offering payments will jeopardize enrollment, rendering FSWs research orphans;
- Individual participants may be subject to community coercion, but a CAB of FSWs has approved the study as in the best interest of their community.

Persons who inject drugs (PWID). PWID are at high risk for HIV and other co-morbidities. Like FSWs, PWID are a hard to reach and socially stigmatized population. Ethnographic interviewing on social (drug) networks and systemic and individual risk factors contributes to development of effective public health policies.

Investigators held focus groups with 100 urban PWID who commented on videos of street recruitment of PWID mentioning payment and of a PWID participating in a study asking for a payment advance (Oransky, Fisher, Mahadevan, & Singer, 2009; Fisher & Goodman, 2009). She noted that standard research payment protections for PWID participants would include studying addiction in economically marginalized communities, consulting with CABs to determine fair payment, and assessing potential participants for inebriation and cravings that compromise informed consent. In some cases, the research might offer to pay or reimburse individuals for travel and invite them to return when they are in a better position to understand the consent process and participate in the study.

Dr. Fisher explored this question: "Should researchers give money to PWID who may use the money to purchase drugs?" Dr. Fisher cited responses such as: "If they're going to get high, they're going to get high; it doesn't matter about the money." She raised the question of

whether ethnographers can justify payment that they know will be used for drug purchases if the research is a minimal risk activity compared to other ways they might obtain money.

Respondents told interviewers that PWID would probably not pay attention to the details of the study in deciding to participate: "I don't care what the questions are about. I'd do anything to get that money." The speaker queried:

- Does the interview relationship between an ethnographer and participant require greater relational obligations?
- Does the investigator's silent acceptance undermine the obligation of informed consent in ways that jeopardize participant protections or knowledge gained?

Community Addiction Research Workers (CRWs). Researchers asked 275 CRW respondents to respond to a survey from initial focus groups. The participants lived in the communities where they worked and had themselves suffered from drug addiction or were living with HIV (Fisher, True, Alexander, & Fried, 2013; True, Alexander, & Fisher, 2017). The study focused on the impact of research payments on participants and how they did their work within the limitations of research payments.

About half endorsed the following statement: "I believe that offering money made some participants ignore the risks of research." The same percentage agreed: "I do not believe that some participants really understood the research they agreed to participate in." Nearly one-third found the payment they received insufficient to provide service referrals and sometimes used their payments to offer incentives for participation. The same number reported feeling overworked, pressured to get high numbers of participants, over-burdened, and emotionally drained.

The speaker asked:

- Are "fair" research payments sufficient in communities with participants in desperate need of health and social services?
- How do we address issues of pay justice when participant economic and health needs place the burden of economic equity on CRWs?
- How do we address the joint effects of participant and CRW economic needs that negatively impact CRW mental health and scientific validity?

Noting that SACHRP has stated that "failure to provide adequate incentives can have a detrimental effect on research and research participants," she queried how payment justice and equity can be achieved when:

- Informed consent is inadequate to ensure voluntary participation,
- Fair payment leads to community coercion,
- Money is used for health compromising behaviors, and
- Research staff (CRWs) bear the burden of participant economic desperation and health equities?

If fair payment is essential to respecting participant time and effort and securing population representative enrollments, she asked, how do we balance harms that arise from the interface between fair payments and participants' lived experience with the obligation to ensure fair access to studies that can inform health policies tailored to the unique needs of economically marginalized communities?

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.

Dr. Wang gave several examples of hurdles to research participation that cannot be removed by payment. The first case study he presented was a 55-year-old Asian female from Laos with locally advanced nasopharyngeal carcinoma who was seen in the oncology clinic at her local safety net hospital. She was offered the opportunity to participate in a Phase III trial for which she was a good candidate. However, she had limited English proficiency and the consent form was available only in English, she lacked reliable transportation and access to communication, she was suspicious of the clinical trial mechanism, and she did not like the randomized nature of the treatment arms that offered no guaranteed access to potential treatment. Even when transportation issues were addressed by community allies, she ultimately declined clinical trial participation due to the number of required visits (labs, procedures, office visits) and the randomized nature of the trial.

Dr. Wang discussed the obstacles that exist in clinical trial enrollment and explored potential solutions to addressing participation burden and trial design concerns. A recent study cited by the speaker explored how remote technology and other tools for decentralization might be employed to overcome the burdens of time and travel, resulting in increased likelihood of enrollment in cancer clinical trials (Adams, Lon & Fluery, 2022). A cross-sectional survey was administered to cancer patients and survivors in the U.S. who had been diagnosed with or treated for cancer in the previous 7 years. The majority of 1183 respondents (60%-85%) reported that they were more likely to enroll if the participation-related time and travel burden decreased as a result of decentralization practices.

Dr. Wang then noted that many novel trial designs are being explored today. He highlighted the use of Real-World Data (RWD) to construct an external control arm, thereby replacing a traditional clinical trial control arm. All participants receive treatment, which effectively removes patients' concerns of being randomized to the control arm. RWD could also help to contextualize trials by providing a better understanding of the intent-to-treat population and helping to enroll appropriate patients in trials.

Dr. Wang also stressed the importance of enrolling underrepresented racial and ethnic populations and cited FDA's draft guidance on the development of diversity plan's (2022). He noted that the guidance "sets a high bar" for research teams. The speaker suggested that the solutions to present-day challenges in achieving diverse participation in research may come in many forms.

Panel Discussion II

- Includes special guest Jill Feldman; Lung Cancer Patient and Advocate, Co-founder of EGRF Resisters

Noting that the second group of presenters complemented the first, moving from the theoretical and ethical to practical issues, Dr. Byrdsong observed that issues related to payment are clearly situational and depend on the context of the research. There is no ”one size fits all” approach and there is no single answer to the concerns raised. However, he believed that as the field continues to consider all the contributing factors it will arrive at a better place.

Invited to respond, Ms. Feldman noted that speakers had raised issues that are well known in the patient community, such as required copays and the need to treat side effects. Some medical centers don't take Medicaid, and there is considerable variation in what insurance will contribute. Many of the problems patients face cannot be resolved by payment alone.

Are participants "investors"? Dr. Byrdsong invited comment on a question from the viewing audience. It concerns the concept of research participants as "investors in the research." From a practical as well as an ethical viewpoint, does this concept address or answer some concerns about payment?

Dr. Largent responded that patients' investment in research includes not simply time and effort but also hope that they will be helped or that they will help others. This is important to keep in mind. They are partners, not people from whom research extracts things it needs. Payment may be part of the participant-investigator relationship, but it is not the end.

Not only the subject, but also the subject's family, invest heavily in clinical trials, Ms. Feldman stressed. Family members may have to take off work to help the subject get to appointments and may experience both the emotional and physical stress of caretaking.

If participation is similar to a financial investment, Dr. Devlin queried, there should be a return on the investment. What happens when the trial ends? What does the patient receive in terms of future treatment? Do they benefit by getting information on their disease or condition, including study results?

Dr. Krutsinger, who is a fan of the show "Shark Tank," said the show featured a character famous for royalty deals. He invited workshop panelists to imagine an industry sponsor for an interventional trial setting aside a percentage of profits from a successful drug to share with the research participants who helped it to bring the drug to market. This would be a little like a lottery ticket, but it could have a significant impact.

Dr. Dickert liked the notion of paying back patients but pushed back against the analogy of patients as investors. When he considers his investments, he does his own research. When an institution oversees research, however, this obligation lies with the institution. He invests money at his own risk and is responsible for the results. A patient is not responsible in the same way and the return on investment does not belong to the patient in the same way. It would be problematic, in particular, to say that patients who enrolled in trials that don't turn out to be

profitable made bad decisions.

Ms. Feldman commented that sharing in financial reward is not the goal of most patients. At the same time, nobody has more "skin in the game" than the patient. Mr. Borasky observed that the nature of the investment depends on the community of volunteers. When the study involves finding an effective treatment for a disease or condition, participants invest in the goal of treatment and hope as a community to achieve that goal. This is different from an individual engaging in a financial transaction for personal gain.

Drivers of burdens on participants. Dr. Byrdsong invited speakers to consider the burdens on study participants that have been mentioned in various presentations, including those caused by state and local laws (for example, the need to access people without using their social security numbers for a variety of reasons). Burdens are multi-layered and have multiple sources. What are the drivers of these burdens and to what extent do we have control over them?

Ms. Feldman noted that there are burdens that can arise at every step in a study, some of which can be controlled by the institution (for example, travel arrangements and assistance managing side effects) and some cannot. With patient involvement, many of them can be addressed successfully.

Ms. Tillman distinguished between those that cannot be controlled immediately, such as the tax code, and those that can. Researchers should start with what they can control and commit to do so. Many of the burdens raised have been discussed for years. What is the research community actually going to do to address them? One example of a possible action would be to create a registry of study participants.

Dr. Ritchie noted that although researchers might not be able to change burdensome laws today, they can make people aware of the negative and unintended consequences of laws, including the tax code, and encourage legislatures to think about the negative consequences of these laws. Dr. Devlin observed that considerations like the preference for being paid in cash would not have occurred to her when she served on an IRB. She urged IRB members to think more holistically.

Dr. Collins opined that for some types of trials, burdens originate from federal rules as interpreted by the IRB. These rules reflect the history and times in which they originated and do not work well in community-based research. As a researcher, she needs the leeway to work with the community involved in the study and make changes as the research proceeds, taking into account repercussions on participants across different populations. The effort to reduce burdens on participants through such adjustments often creates burdens for investigators. IRBs often don't understand the complexity of this type of research. Oversight structures need to be more flexible.

Thinking back to the origin of the Common Rule, Dr. Byrdsong recalled that one of the studies that spurred its creation was the landmark case of untreated syphilis – which heavily involved payment. Subjects received free room and board and a nice funeral as inducements to keep them involved. Mr. Borasky noted that financial incentives used to keep people in an unethical

study should not be confused with fair payment for people participating in an IRB-approved study in which the risks and burdens have been assessed as reasonable. The situations are very different. Dr. Byrdsong agreed, noting that payment in itself is apparently neither good nor bad. It depends on the situation.

Ms. Feldman cautioned that beneficence is not solely about avoiding harm but includes benefitting patients and promoting their welfare. IRBs need to consider benefits as well as risks.

Many of the payment-related burdens discussed in the workshop are not imposed by either law or regulation, Dr. Largent observed. Instead, they are "problems of our own creation," notably by IRBs' conservative interpretation of regulations, which reflects uncertainty and worry. The regulations make it possible to do what is right in most cases. There is, however, room for improvement—for example, it would be great to exclude research-related payments from benefit eligibility determinations.

Dr. Dickert underlined the perception that many difficulties stem from convention rather than regulation or law. For example, there is a disconnect between the informed consent document and the patient's interactions with interviewers at the enrollment stage. The consent documents seem to be full of warning flags that seem to be trying to discourage enrollment, while the person seeking consent seeks to facilitate appropriate engagement. This creates a really disconnected narrative for patients. Many IRBs do not even allow researchers to describe potential benefits. If we as researchers are asking people to participate, he said, we need to believe in the value of the research. If we need to pay too much to encourage them to participate, we are probably asking them to do something they won't like. He observed that the needle between engagement and protection has moved somewhat toward engagement, but it could move a lot further.

Dr. Devlin agreed. Why do researchers that trust the IRB to approve research worry about the harm that could be caused by paying participants? We need to rely on IRBs to do their job, she said, and worry less about how payment might create unfair incentives to participate in perfectly fine research. Mr. Borasky probed the question of how research became "special" in this regard. "When we pay an Uber driver or a waiter, do we worry about how they might use a tip? When a person is considering a job, do we advise them not to take the one that pays more because it might be exploiting them?" Dr. Byrdsong quoted a character in the movie "Wall Street": "Anything worth doing is worth doing for money."

Ms. Feldman said that researchers that simply grab a template for informed consent are participating in a fear-driven cycle that benefits no one. From the subject's perspective, so much could be taken out of typical informed consent forms!

Dr. Gelinas advised that the effort to provide better compensation for participants should go hand in hand with addressing and improving other aspects of research participation. He noted that the "elephant in the room" was the lack of guaranteed compensation for research-related injury, which is one way in which research participation is disanalogous to employment, where worker's compensation plans for work-related injury are typically required by law. Dr. Gelinas

voiced some unease about agitating too strongly for higher payment rates when participants may have no way of being financially restored if they are injured as a result of participation. Dr. Devlin agreed and stressed the need for change regarding typical approaches to injuries stemming from research participation.

Dr. Byrdsong gave two personal examples of payment and reward for research participation. His father, in the final stages of cancer of the prostate and larynx, wanted to participate in a trial to help other people and had no interest in either payment or risk. A nurse colleague, on the other hand, told him she needed to do another trial so that she could get enough money to buy hardwood floors. It seems almost comical to think we can really understand the motivations of individual patients.

People make decisions about treatment based on what is important and meaningful in their lives at the time, explained Ms. Feldman. A young mother with young kids would do anything to stay alive and raise her children as long as possible regardless of side effects. An older retired person whose main pleasure in life is gardening or playing piano may reject a potential treatment that causes neuropathy and would make these delights impossible.

Which wallet is the source of payment? Dr. Byrdson asked whether it matters what wallet is the source of the money used to pay participants. A "Big Pharma" company sponsoring a trial may stand to make a lot of money if the tested drug makes it to market. Social-behavioral research may have much lower funding levels and potential financial rewards may not exist.

Dr. Abadie said that justice and reciprocity should always be considered and researchers should always seek to understand what matters to participants. On the theme of justice, Dr. J. Fisher commented that commercial research is done not only to benefit the public but also for commercial benefit. This changes the nature of the conversation about rewards for research participation. Equal and equitable access to an effective medication developed through research may not exist.

It is respectful to pay what you can, Dr. Dickert advised, even if that may not be much. For example, a graduate student might be operating on a shoestring budget. Even so, appropriate payment should be a considered, even if it isn't ultimately doable. More attention needs to be paid to clearly inappropriate incentives for participation, such as when physicians who are investigators capitalize on their relationships with patients.

Dr. Largent said payment is often not in line with the social value of studies. Looking across studies, those that offer more payment do not necessarily hold more promise for social benefit. It is helpful for the IRB to consider what is happening between. Too often, IRBs do not rationalize study portfolios.

Dr. Ritchie said that transparency is needed about how patients are being reimbursed. She suggested that clinical trials.gov should require a record of subject payment. This is not done consistently. Dr. Largent agreed. If this were done, investigators and participants might have a better sense of what is fair and IRBs might be more comfortable talking about payment because they have a sense of broader practices.

Ms. Feldman stressed that potential participants with specific diseases or conditions often beg for the opportunity to work for free. They are more concerned about ensuring that their voice is seen as credible and their input valued, as well as having the opportunity to participate in designing promising research, than they are about how much they are paid.

Input from participants about payment. Dr. Byrdsong wondered whether there should be a mechanism for researchers to get input from potential participants about payment. Is this appropriate? What would it look like?

Dr. Ritchie said patient advocates have had an impact on patient involvement and setting expectations in this area. She sees the tide turning, but the process of change needs to go further. Ms. Feldman agreed that the situation has improved but stressed the need for a structure. It is still usually the case that researchers consult participants, if at all, when the protocol and procedures have already been finalized. Something so important should not be an afterthought. Dr. J. Fisher stressed that in a true partnership, patient voices should actually influence the study design or conduct. Otherwise, researchers may inadvertently add burdens on research participants in getting their feedback with no benefit to the participants themselves.

Dr. Collins pointed to the fact that the way grants are usually awarded poses a significant barrier to patient involvement in protocol development. When researchers are developing their proposals, they usually do not have any money to pay CABs or other partners to consult with them. Without the ability to reimburse them for their time, too often researchers follow tokenistic approaches that are much less effective. Ms. Feldman underlined the principle that local boards and partners should be paid for the years of experience they offer.

Ms. Tillman reflected that every IRB has an unaffiliated member. She wondered whether this member could be a community voice and encourage appropriate payment. IRBs should empower these members to help them look at research through the lens of a participant. Dr. Byrdsong added, however, that there is no regulatory requirement that the unaffiliated member be a representative of a community.

Dr. Wang wondered whether the nature of the problems the workshop has explored stem in part from a misalignment of goals. Researchers want to develop a study that passes muster and gets funded, so they try to pack as much as they can into the study. Patients' goals may be very different. The different perspectives can only be aligned through a two-way conversation.

Ms. Feldman urged researchers to change their mindset and ask the right question – not how can I get more people to participate, but why aren't we designing trials in a way that would allow more participants to participate? If that is done, it will help align goals more closely.

Closing remarks. Dr. Byrdsong thanked OHRP for sponsoring the research, expressing the hope that this workshop is the beginning and not the end of conversation on the topic.

Observing that Exploratory Workshops are now in their fifth year, Dr. Lau thanked all the

panelists for their commitment as well as the hundreds who watched online. She heard clearly that there was no one solution for all situations, and addressing this challenge will "keep us on our toes." She added that the topic of unreadable informed consent documents, which was raised repeatedly, was "near and dear to her heart." She hoped that over time this challenge, too, will be addressed.

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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.

Session II

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.

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