

# Payment for Research Participation: Takeaways from OHRP's 2022 Exploratory Workshop

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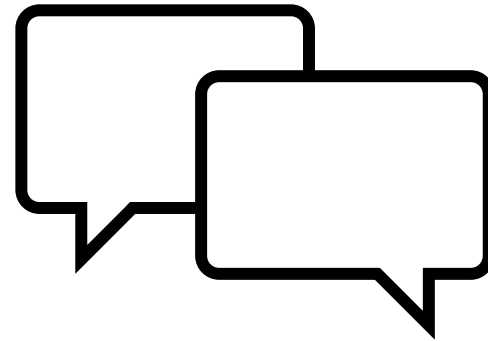
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# Disclaimer

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- The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S. Department of Health and Human Services.



# Overview

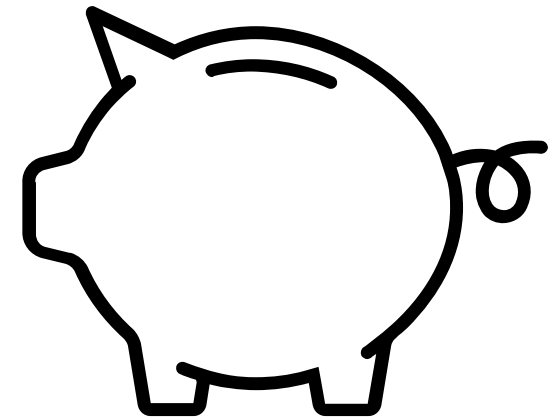
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- Introduce relevant regulatory requirements
- Describe OHRP's current guidance, advisory committee recommendations, and OHRP's planned actions
- Summarize the 2022 exploratory workshop on payment for research participation

# Payment for Research Participation

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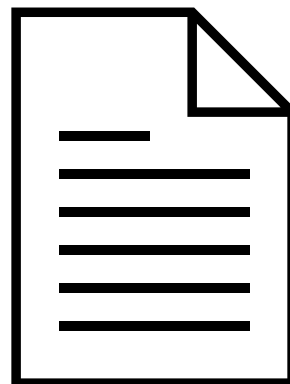
- Investigators may want to pay individuals for participating in research in order to...
  - Reimburse them for out-of-pocket costs.
  - Compensate them for their time and effort.
  - Show appreciation for their participation.
  - Incentivize their enrollment or study completion.
  - Conduct research on payment and human behavior.
- Type or intent of payment is an important consideration.



# Human Research Protection Requirements

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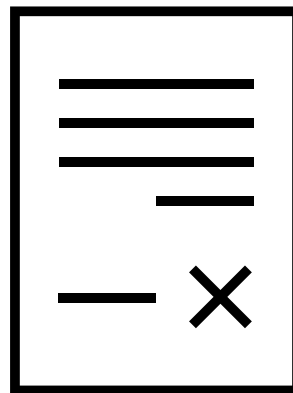
- The regulations at 45 CFR 46 are *relatively* silent on payment.
  - For research that involves more than minimal risk, informed consent must explain whether any compensation is available if injury occurs (45 CFR 46.116(b)(6)).
  - When appropriate, informed consent must describe any costs to the subject that may result from research participation (45 CFR 46.116(c)(3)).



# Human Research Protection Requirements

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- Institutional Review Boards (IRBs) often examine plans to pay participants with 45 CFR 46.116(a)(2) in mind:
  - *An investigator shall seek such consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.*



# Current OHRP Guidance and Advisory Committee Input

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- OHRP’s published Frequently Asked Questions (FAQs) signal caution:
  - “[Remuneration] will be more important to those for whom it will make a significant financial difference. Thus, **IRBs should be cautious** that payments are not so high that they create an ‘undue influence’...”
  - “...**IRBs must be sensitive** to whether any aspect of the proposed remuneration will be an undue influence, thus interfering with the potential subjects’ ability to give voluntary informed consent.”
  - “Reasonable assessments can be made to minimize the likelihood of undue influence or coercion occurring. For example, **IRBs may restrict levels of financial or nonfinancial incentives** for participation...”
- OHRP’s FAQs also include other information important to the current discussion. In particular, IRBs should not consider compensation or remuneration as a way of offsetting risks. This continues to be OHRP’s position.

# Current OHRP Guidance and Advisory Committee Input

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- The Secretary's Advisory Committee on Human Research Protections addressed this in 2019 and 2021, respectively:
  - *“[Given lack of tools] [c]ombined with the directive from regulators to ‘be vigilant,’ some IRBs may take a ‘better safe than sorry’ approach that prioritizes avoiding undue influence but fails to give adequate consideration to other important goals.”*
  - ***If the risks and potential benefits are appropriately balanced and the rights, interests and safety of subjects are protected, it is not clear what standard would establish a financial influence as “undue.”***
- Reflects tension between protecting individuals and groups from exploitation and reducing barriers to study inclusion.
- Signals that oversight bodies should not view payment as offsetting study risk – consistent with OHRP's position.



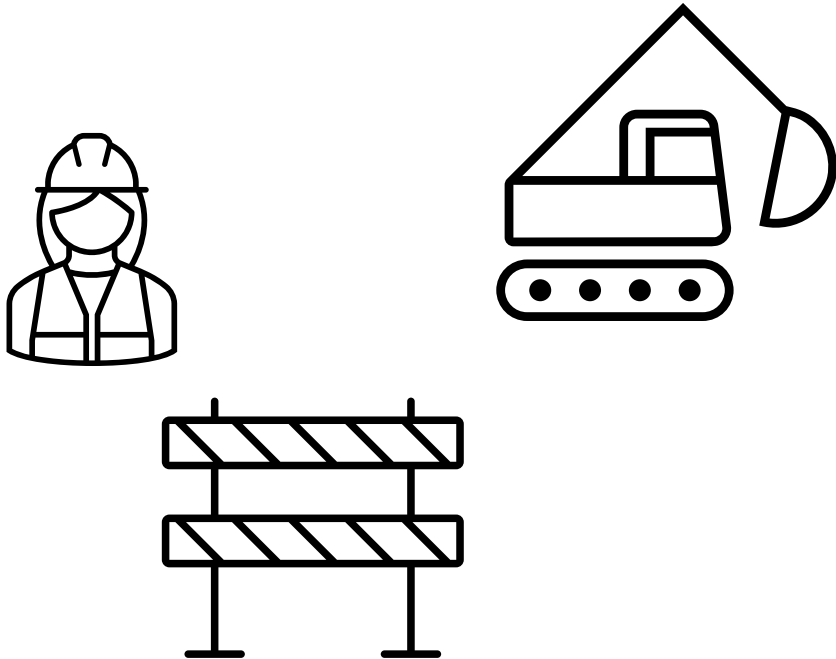
## In a Nutshell

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- Investigators and IRBs may be concerned that paying participants could unduly influence people to enroll in the study.
  - At odds with the principle of “respect for persons” in research participation.
  - Could lead to regulatory noncompliance with 45 CFR 46.116(a)(2).
- However, lack of payment can be a barrier to research participation.
  - At odds with the principle of justice in research protections.
  - Barriers that influence study inclusion may also impact the “generalizability” of the research.
- Beyond ethics and regulations, there can be practical considerations.
  - When, how, how much, for what?

# Related OHRP Activities

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- We are drafting updated FAQs.
  - Our goal is to publish these as draft for public comment.
  - Stay tuned!
- **We hosted an in-depth workshop to explore this topic.**
  - Experts in ethics, policy, law.
  - Investigators who have taken evidence-based approaches.

## 2022 OHRP Exploratory Workshop: *Beyond Altruism – Exploring Payment for Research Participation*

*“Participants in research should reflect the diversity of our population, including race, ethnicity, sexual orientation and gender identity, age, sex, genetics, socio-economic status, educational background, geographic location, and so forth...Financial barriers are often cited as a key reason for why research participation is out of reach for many...”*

-ADM Rachel Levine, M.D., Asst. Sec. for Health



**Read ADM Levine’s full blog post here:**

<https://www.hhs.gov/blog/2022/09/06/ohrp-exploratory-workshop-beyond-altruism-exploring-payment-for-research-participation.html>

## Workshop Objectives

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- 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
- Identify the logistical and practical considerations for paying research participants

## Exploratory Workshop: Online Resources

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- Detailed summary report, references, speaker bios
- Workshop slides and videos
- Certified IRB Professional credit
- Everything is online: <https://www.hhs.gov/ohrp/education-and-outreach/exploratory-workshop/2022-workshop/index.html>

# Explore the notion of payment for research participation in the context of justice

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- Concerns about payment inappropriately influencing participation is not a new issue, but the conversation is evolving to include distributive justice.
  - Debates can be rooted in stigmatizing notions of capability and capacity.
  - The approach to “respect for persons” needs to evolve.
- Empirical evidence should inform discussions.
  - Who participates in which types of studies, and what is their motivation?
  - How do potential enrollees view payments in the context of deciding to participate?
- Important to consider the relationship between payment, power, and privilege in the research enterprise.
- Underlying inequalities may lead to differential influence of payment.
- In general, if paying can support fair access to both participation and the social good of research results, there is a strong reason to pay.

## Examine what IRBs think about payment for participation

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- Useful empirical data exists on this topic.
- Payment can influence participation, but when is that influence “undue”?
  - Many IRBs are unsure about this and take a “better safe than sorry” approach.
  - IRBs are attuned to both the ethical and regulatory implications.
- Even when allowing incentive payments, IRBs may restrict the advertisement of such payments.
- Some IRB members worry payments incentivize dishonesty in eligibility screening – more evidence is needed.
- IRBs should not view payment as offsetting study risks for purposes of review and approval.

# Examine what research participants think about payment for participation

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- Many factors can motivate research participation – not just payment.
- Fair compensation is important – and not all forms of payment are the same.
  - Payment may be *one part* of building trust.
  - Gift cards may be viewed as paternalistic, stigmatizing, inadequate.
  - Payment amount may be a “signal” to prospective participants about the study risk.
- Others involved in research expect to get paid – why not participants?
  - Subjects are experts – not simply volunteers.
  - Some subjects perceive research as “transactional” and themselves as part of the gig economy.
- Participants – not just IRBs and investigators – recognize concerns with targeting low-income groups.



# Describe the financial burdens of participation and possible ways to address them

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- Out-of-pocket expenses (e.g. travel, parking, childcare) can be a barrier.
  - Reimbursing these expenses can help.
  - Not all participation burdens are financial.
- When considering what motivates participation...
  - Move away from either/or view of payment vs. altruism.
  - Move toward addressing structural and individual barriers to inclusion.
- Ask questions and be willing to learn from involved communities.

# Identify the logistical and practical considerations for paying research participants

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- Different goals of payments may lead to different implementation models.
  - Inducement for participation, “gig economy” work, appreciation payments may be implemented and perceived differently.
  - “Completion bonuses” merit unique considerations.
- Payment may impact participants’ taxable income or benefits eligibility.
- Requiring SSN for payment may add risk.
- For multisite research, local considerations may influence proposals for the amount or means of payment.
- Payment is not a substitute for ongoing care or post-trial access to treatment.
- Investigators/IRBs cannot control all of these factors – start with the things that they can control.

# Overarching Themes

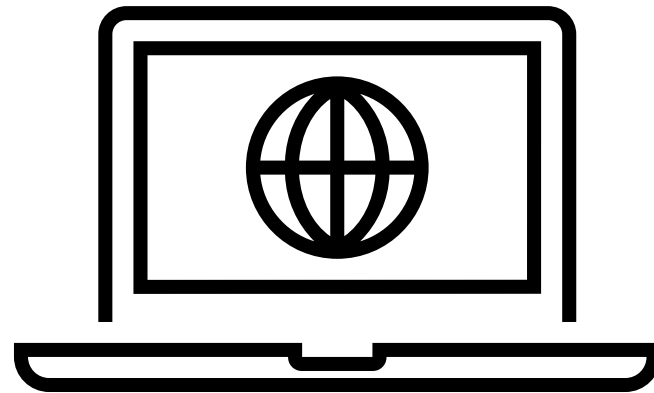
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- The needle has moved toward distributive justice.
- The regulations are not seen as an obstacle to new approaches.
- Payment does not offset risks or “compensate” for deficiencies.
- Autonomy in research protections is nuanced.
- Empirical data on undue influence are reassuring so far – so the burden of proof should shift to those who discourage incentives.
- Two sides to payment and exploitation:
  - Minimizing compensation may avoid disproportionately influencing participants of lower socioeconomic status to participate, but...
  - This may add barriers, or lead to the same people participating for less payment.
- Payment alone is not sufficient to ensure equitable subject selection.

## Reminder to Explore the Online Materials

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<https://www.hhs.gov/ohrp/education-and-outreach/exploratory-workshop/2022-workshop/index.html>



# Acknowledgement to Workshop Participants and OHRP Staff

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**Thank you!**

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