OREGON CLINICAL & TRANSLATIONAL *Research Institute*

OCTRI Research Forum

Research Participant Compensation

Recruitment Considerations, IRB Requirements, and Best Practices

---

DATE: November 14, 2024 PRESENTED BY: Meredith Zauflik, MPA, OCTRI Recruitment Program Manager; David Holmgren, IRB Manager; Kise Bond, PSM, IRB Specialist; Paul Newton, IRB Chair

Research Participant Compensation Topics Covered

- Compensation Considerations
- Operational Considerations & Best Practices
- Regulations/Guidance
- IRB Considerations
- Ethical Concerns

OHSU

Financial concerns matter to potential participants and impact enrollment and retention

2023 Global Patient Perceptions Survey by CISCRP and Greenphire showed*:

- **60%** of participants **expect reimbursement** for all out-of-pocket expenses and believe they're not responsible for costs
- **56%** of those who have never been in a trial state knowing potential costs and reimbursements **impacts their enrollment** decision
- Top financial disruptors to trial participation – **missing work**/salary, **not receiving compensation** for their time, and **not being reimbursed** for their expenses

*Greenphire. (2024). *Global Patient Perceptions & Engagement Preferences in Clinical Research* [White paper]. https://www2.greenphire.com/l/905172/2024-03-26/3nhcsb/905172/1711488061r0YjKhCQ/CISCRP_2024_Survey_Results_FINAL.pdf

OHSU

Why compensate participants?

Compensation matters to:

- Increase enrollment numbers and retain participants
- Recognize participant contributions and show appreciation
- Ensure equitable outcomes through broader representation
- Avoid exploitation, especially of those from vulnerable populations
- To reimburse expenses

OHSU

What are those financial concerns and considerations?

Think about your study population - What does their life look like? What concerns and barriers may exist to their participation?

- Work
- School
- Family/children
- Economic status
- Insured or not
- Geographic location
- Mode of transportation
- Other concerns and barriers

OHSU

Addressing concerns and considerations (non-monetary)

- Provide childcare
  - Staff watches children during study visit or schedule for babysitter to come to campus
- Transit passes, taxi vouchers, or schedule a ride share (e.g. Uber Health)
- Flexible/later in day study visits
  - Accommodate to work and school schedule
- Limit on campus time, move to online and telehealth as able
- Provide internet or cell phone service
  - Study requires online or in-home intervention

OHSU

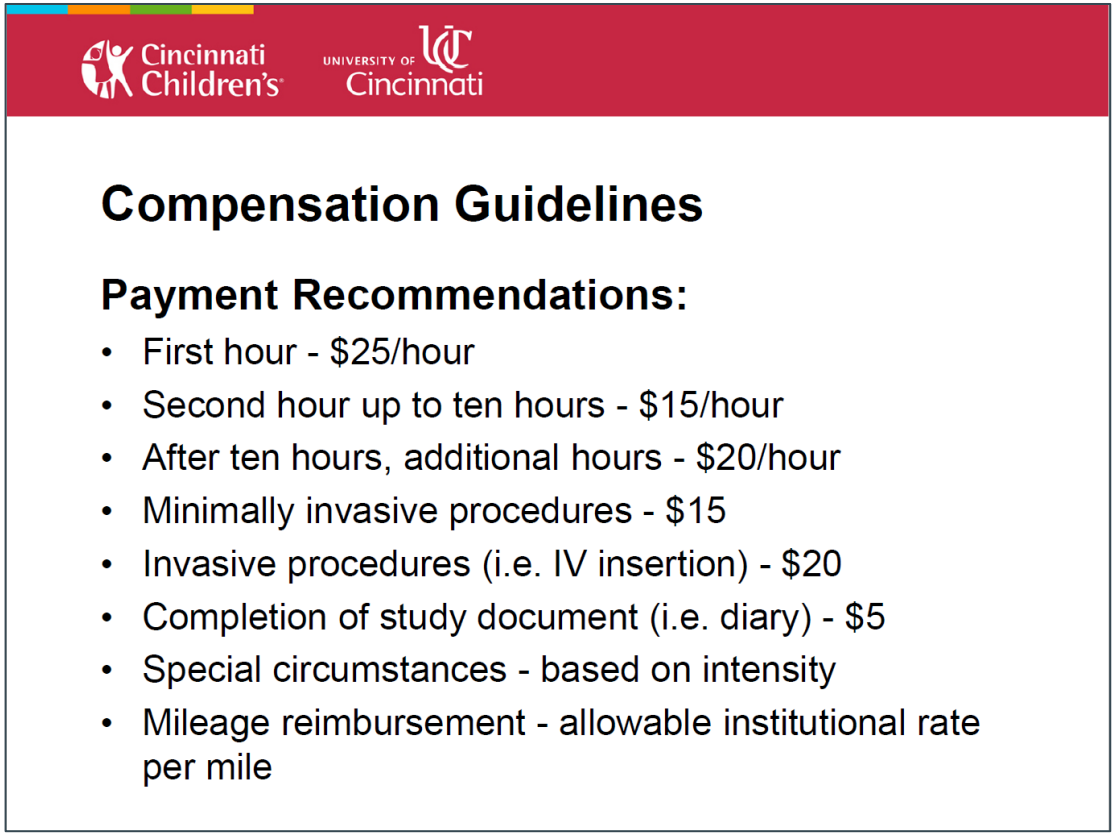
Determining monetary compensation amounts

When creating compensation plans, take into consideration:

- Participant's time commitment to study
  - Number of visits, travel time, diaries/surveys
- Participant's inconvenience/burden
  - Time off work, procedure prep (e.g. colonoscopy)
- Standard of care for disease/condition
  - If procedure(s) would be done anyway, compensation should be based on study-related activity(ies)

OHSU

Example from Cincinnati Children's Hospital/UC Health*



*Cincinnati Children's Hospital/UC Health. (2012). *Participant Compensation: Ethics, Taxes, and Common Practices* [PowerPoint slides]. https://cctst.uc.edu/sites/default/files/2012/Slides%20Hoctor%202012-02-17.pdf

OHSU

Varying payments

It may be acceptable to vary payments among participants based on the costs they individually incur:

- Example: Hotel, food and travel costs if participant travel is far
- Allows individual needs to be addressed without over incentivizing those who don't have the same participant cost
- Aim to be a break even, not a net benefit via reimbursement
- Reminder - Study teams who choose this option need to create a plan to manage reimbursements

OHSU

Determining payment schedule

When creating compensation schedules, take into consideration:

- Length of study
  - One time? Couple months? Multiple years?
- Amount of study visits
  - Monthly? Weekly? Multiple a week?
- Key time points of study
- Completion of visits or certain procedures
- Timing of payments per visit, month, quarter, etc.
- Varying amounts per timing of payment
  - Same? Different? More at beginning or end?
- Payments at end of study to increase retention

OHSU

Audience Participation

Below are possible participant payment schedules for a 2-year survey study offering $125 total compensation. Which is the best option?

Visit	Option 1	Option 2	Option 3
Baseline	$10	$15	$20
6 Months	$10	$20	$0
12 Months	$10	$25	$40
18 Months	$10	$25	$0
24 Months	$85	$40	$65

OHSU

Participant payment methods at OHSU

- ClinCard, check and gift cards are the allowable participant payment methods at OHSU
- Consider study population, compensation amount, and payment schedule to determine the best and allowable method for your study
- Compensation methods:
  1. ClinCard
     - Reloadable prepaid debit card
     - Payments over $150 require SSN to be collected
  2. Disbursements/checks
  3. Gift cards
     - Only allowed for one-time payments up to $150
     - Does not require SSN to be collected, but study teams must track gift card disbursement
- For more information, visit OHSU's CFS Research Subject Payments policy

OHSU

Participant Non-Cash Payments/Incentives

- Equipment and other gadgets/tools may be part of the study compensation
  - Example: Participants getting to keep an activity watch

- This is considered an incentive and should be included as part of the total participant compensation

OHSU

Regulations

- There are no specific participant compensation regulations; however, regulations do require that researchers obtain consent under circumstances that minimize the possibility of coercion or undue influence (45 CFR 46.116(2))
- Payment is not considered a benefit but is a recruitment and retention incentive
- Payments cannot be used to offset risks

OHSU

Guidance

- 2018 FDA Information Sheet Payment and Reimbursement to Research Subjects

- 2019 SACHRP Recommendations to HHS Secretary: Addressing Ethical Concerns Offers of Payment to Research Participants

OHSU

Ethical Anatomy of Payment for Research Participants (Rozynska 2022)

- Social beneficence
  - Enhances recruitment and retention rates by removing economic entry barriers
- Respect for Autonomy
  - Enables realization of individual's free will to participate in research by removing economic entry barriers
- Individual Beneficence
  - Reduces risk of participation having a negative impact on the subject's economic position by making participation a cost-free activity.
  - Improves access to potentially beneficial research
- Justice
  - Reduces inequality of opportunities for an individual with low socioeconomic status by removing economic entry barriers

OHSU

Participant Payment Terminology

Participant payment terminology varies across guidance documents.
Here are some examples of different categories of participant payments.

Compensation – amount paid for time (visit, time to complete diaries/surveys), inconvenience and study burden

Reimbursement – amount paid for direct costs such as travel expenses to and from the study site and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence

Incentives – payment to participants to motivate them to take advantage of grant supported health care. They go beyond reimbursement to encourage recruitment and may include things such as keeping study equipment

Appreciation – small token to express appreciation for participant's study participation. These could be small gifts such as chocolates, cups, tote bags, movie tickets, that have minimal value so likely have zero impact on recruitment (Grady 2005)

OHSU

IRB Review

- Per OHRP guidance, IRBs should consider several factors when evaluating the acceptability of payments:
  - IRB responsibility to approve research only when risks are reasonable in relation to benefits to participants and/or society. That is, the IRB has already found the risk/benefit ratio to be acceptable regardless of payments to subjects.
  - The possibility that incentive payments will compromise the informed consent process;
  - Steps that can be taken to support autonomous decision-making in those contexts;
  - Tradeoffs that may be associated with restricting incentive payments and how that may affect achieving adequate recruitment; and
  - How similar payment might be viewed outside the research setting.
- Although IRBs do not consider payment a benefit of the research, they should be aware that potential participants likely will

OHSU

What the IRB Needs to see

- Protocol - Compensation plan should be practical and consistent with study team goals
  - Declaration of Helsinki states the protocol should contain “incentives for subjects”
- Consent should present compensation plan in a way that is clear to subjects
- Multicenter trials – this information should be included in the Local Conduct Supplement
- Waived studies should use the same considerations

OHSU

Payment Schedules

- Payments should be based on visit/procedure completion
  - Screening, visits, early termination, sub-study participation, etc.
- Payment amounts and timing should be clearly outlined in protocol and consent form
  - Prorated payments
  - Differential payments

OHSU

How does the IRB analyze this?

- Examples
  - $300 raffle for participating in 30 minute survey. 1:200 chance of winning
  - Up to $1220 with $20 for screening and $50 per visit including blood draw and ultrasound. 25 visits total

OHSU

Other Payment Considerations

- What to do if the participation may be fraudulent/bot
- Language in consent form
- No or low subject compensation
- Change in funding/budget

OHSU

Sharing PHI to Process Payments

- If you need to share PHI (email, phone#s, etc) to a third party to process payments/gift cards, the third party needs to be listed in the consent form. Example consent language from IPS:

As part of the study, OHSU has engaged with a vendor, [insert name of vendor], to process and send you your compensation. The study team will send your personal information (like name, address, email address, etc.) to coordinate payments to you. You can choose to receive email communications from [insert name of vendor] to the personal email address you provide. These messages may contain information that you wish to keep confidential. Most modern email systems send and receive emails securely. However, your personal email provider may not be able to accept secure emails. There is a risk that those unsecure emails could be intercepted or viewed by other people and would no longer be confidential. There is also a risk that emails could be misdirected or viewed by other people who have access to your email account.

If, at any point, you no longer wish to receive emails from Vanilla Gift Card, tell the study team by sending an email to [insert study contact email] or calling this number [xxx-xxx-xxxx] and they will stop sending you emails.] When your information is released to [insert name of vendor] it may no longer be protected under federal or Oregon law.

OHSU

IRB & Recruitment Resources

- IRB
  - Check out the IRB policies and forms webpage for more information and resources for researchers
  - Email irb@ohsu.edu for questions and assistance

- OCTRI Recruitment
  - The OCTRI Recruitment webpage is a great resource for recruitment and retention related information, guidance and additional resources
  - Email octrirecruitment@ohsu.edu for questions, support, or to request a complimentary recruitment consultation

OHSU

References

- WMA Declaration of Helsinki (2024)
- Grady Christine. Payment of clinical research subjects. *The Journal of Clinical Investigation.* 2005;115(7):1681–1687. doi: 10.1172/JCI25694. [PubMed]
- Rozynska, J. (2022) The ethical anatomy of payment for research participants Med Health Care Philos. 25(3): 449–464. Published online 2022 May 24.
- NIH 3014-302-Subject Recruitment and Compensation (2024)

OHSU