Participant Payment Guidelines

For additional guidance or questions, contact inhealth@iu.edu



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# Introduction

The following document provides general guidance on commonly asked questions related to research participant payments. For further guidance or additional suggestions email inhealth@iu.edu. You may also reach out to any of the contacts listed for various departments on specific questions.

# Coercion vs. Undue Influence

Investigators should keep in mind the definitions of coercion and undue influence when considering participant payment amounts**.**1

* **Coercion** involves an intentional **threat of harm** that influences decision-making and undermines informed consent
* **Undue influence** involves an **offer of something desirable** that distorts decision-making and undermines informed consent.

*\*\* Given this, the main ethical and regulatory concern with offers of payment is undue influence, not coercion.*

# Types of Incentives and Compensation

Investigators should keep in mind the **Types of Payments** available and allowable:

Reimbursement for out-of-pocket expenses: generally acknowledged to be an ethically acceptable way of restoring subjects financially to their baseline.

* Investigators should offer to reimburse participants for the costs associated with participating in the study (parking, transportation, lodging, food, childcare etc.) unless funding for reimbursement is not available.
	+ Examples
		- Offer parking vouchers and/or bus passes at each visit. Alternatively, reimburse for the approximate cost of parking and travel expenses via gift card provided or re-loaded at each study visit. Do not wait to reimburse for those costs because participants are incurring costs each visit and would have to pay out-of-pocket.
		- For a multi-day visit, participants who travel from out of town should be reimbursed for lodging and meals.

Compensation for time and burdens: a way of compensating participants for the time they spend in the study and the research-related burdens they undertake.1

* Investigators should also plan to compensate participants for the time they are being asked to give and the burdens they are asking participants to take on. This could be looked at as an “hourly wage.” Investigators should consider the average local hourly wage and estimate the number of hours participants will spend in the study deciding how much to pay research participants. Consider local and federal standards for average hourly wage, industry standards for participants with a specific skillset or knowledge base that the study will benefit from.
	+ Examples
		- A 20-minute interview has a different time commitment and burden than an overnight stay with medical procedures, and it is appropriate for payment amounts to differ in accordance with the time and burdens in each scenario.
		- Some studies have higher risks, higher topic sensitivity, and more specific eligibility criteria that also contribute to the level of burden investigators should compensate for. Burdens for healthy individuals may be less than that of someone who is undergoing treatment for, or recovering from, a specific disease.

Recruitment Incentives**:** Payment offered to incentivize enrollment and improve participation rates beyond reimbursement for out-of-pocket expenses and compensation for time and burdens.

Completion Bonus: To encourage participant retention and study completion, investigators may consider an additional payment or a larger payment at the end of the study if all study activities are completed (“completion bonus”). Do not withhold payment for those activities that are completed.

* + - Examples
			* For a four-visit study in which data collected at the final visit are key to answer the research question, it can be appropriate to pay more for the final visit than for previous visits. For example: to encourage study completion, visits 1-3 could pay $40 for each visit and visit 4 could pay $60.
			* For a study with multiple data collection points, it can be appropriate to offer a completion bonus if all activities are completed. For example: a phone interview and online survey will each pay $40, and if a subject completes both activities they will receive an additional $20 payment.

# How Much to Pay Participants

Investigators should look at what is a reasonable payment amount by considering local cost of living expenses, wages, etc.  There is often unnecessary concern about paying too much when most studies underpay as they do not consider risk, participant burden, etc.2

* Consider paying more to populations that are underrepresented or challenging to recruit; especially when increasing diversity of the participant pool or balancing enrollment across demographics.
	+ Resources
		- Contact HRPP for guidance on different payment amounts: <https://research.iu.edu/policies/human-subjects-irb/index.html>
		- Contact Indiana CTSI for additional guidance on payment amounts and justification for those amounts that you are concerned may be considered potentially unduly influential: <https://indianactsi.org/researchers/services-tools/>
		- The IRB will have final approval on appropriate payment amounts.
* Investigators should not offer a lower payment amount to research participants based on the direct benefit a research participant may receive.3,4
* Investigators should evaluate the burden and/or risk to the participant regardless of direct benefit they may receive.

Hourly Wage Models Investigators can use an hourly wage model for the anticipated duration of study visits. Consider local and federal standards for an average hourly wage and/or industry standards for participants with a specific skillset or knowledge base that the study will benefit from.5,6

* + Examples
		- For low-risk studies, it may be appropriate to pay participants $25 per expected study hour duration to compensate for their time and incentivize them to participate based on local expected wages.6
		- Investigators can offer payments for recruitment. For example, when recruiting a population that may be challenging to engage, consider “snowball” recruitment.

# Equitable Participation

When paying research participants, investigators should make sure participants fully understand the research they are consenting to participate in.  This is especially important for studies that offer a higher payment amount.  The consent process should fully explain the payment amounts and process so that participants understand how, when, and how much they will be paid.

* Investigators should treat participants fairly in reimbursing out-of-pocket-expenses and compensation. This includes paying different groups in the same study the same rate for doing the same activities. (For example, do not pay a teacher less than a pediatrician if they are doing the same study activities.)

# IRB Guidance

In the IRB Protocol Submission, delineate payment into reimbursement, compensation, and incentives categories.  *It is not suggested to delineate in the informed consent, as it can be confusing*.

* Examples:
	+ - *IRB Protocol Language*: Participants will be reimbursed for parking expenses at each study visit with a voucher for the parking garage. For each visit, they will be paid $40 to compensate for their time and a $10 incentive, for a total of $50 per visit. For all five visits, they will receive a total of $250 as compensation and incentives.

*Informed Consent Language*: You will receive $50 for each visit, up to $250 if all five visits are completed.

For specific guidance on Recruitment and Informed Consent, policies and guidelines are below:

* + - HRPP Policy on Recruitment: <https://research.iu.edu/policies/human-subjects-irb/recruitment-of-human-subjects.html>.
		- HRPP Guidance on recruiting human subjects: <https://research.iu.edu/compliance/human-subjects/guidance/recruitment.html>
		- HRPP Policy on informed consent: <https://research.iu.edu/policies/human-subjects-irb/informed-consent.html>
		- HRPP Guidance on informed consent: <https://research.iu.edu/compliance/human-subjects/guidance/informed-consent.html>

# Resources for Budgeting

Consider all associated costs for participants in the study budget. This includes payment, incentive, travel, lodging, hospitality, and cost of procedures.

* Resources:
	+ Reimbursement for out-of-pocket travel expenses
		- Mileage: use Chrome River in One.IU *(will need to add subject to payment system)*
		- Hotels: recommend using IU direct billing for hotels <https://travel.iu.edu/hotel/hotelrates.shtml>
		- Contacts for cost estimates:
			* For IU Health Procedures- Clinicaltrials@iuhealth.org
	+ Parking:
		- IUPUI Parking: for more information on validations, visit <https://parking.iupui.edu/parking/permits/index.html>
		- Denison Parking – visit <https://denisonparking.com> or Tonya Moody tmoody@denisonparking.com
	+ Meal vouchers:
		- IU Health Nutrition: booklets of 50 $6 meal tickets with six-month expiration, billed as used. Must process request with PO. Paige Thompson - nthompson13@iuhealth.org

# Payment Options and Tax Considerations

Indiana University is currently working on updated tax guidelines for participant payments. Below are some general considerations. Specific questions can be directed to the IU Tax Office.

* IRS Form W-9 should be completed for each participant.
* Reimbursements are not taxable.
* Compensation, incentive payments, and completion bonuses are taxable.
* Paying participants in an anonymous study or in a population with mistrust: it may be more appropriate to pay with cash than to use Advarra participant payments if payment amounts are low.
* When receiving W-9 and other forms, securely store and destroy as you would research files (consent, HIPAA, etc.), but do **NOT** store them with study files for data protection. IU Tax Department does not currently request them. Under IU Data Management policies, these are considered critical data. (<https://datamanagement.iu.edu>).

## Allowable mechanisms for payments at IU:

* + Advarra Participant Payments: *primary payment option.* <https://ocr.iu.edu/advarra-participant-payments/>
		- * Children: if the child is age 14-17, the child should complete Form W-9. If the child is under age 14, the parent/guardian should complete Form W-9.
			* Participants without a Social Security Number (undocumented workers, people in the Amish community, etc.): enter “NRA” or “Amish” in SSN field.

### Cash: *confirm with your departmental resources and guidelines to determine if this is an acceptable form of payment*

* + Buy.IU: *requires participant to register as a vendor*
		- Gift Cards
		- Reimbursement for travel, lodging, etc.

### Non-monetary incentives/payments

* + Items purchased must meet IU Purchasing policy: <https://policies.iu.edu/policies/fin-purch-05-prohibited-purchases/index.html>
	+ For specific questions please contact the IU Office of Procurement Services: <https://purchasing.iu.edu/index.html>

## Paying Special Populations

When considering participant payment for vulnerable populations, also consider special populations who do not have a social security number (e.g., undocumented workers, Amish, homeless, etc.).7

# References

1. Harvard Catalyst Guidelines: <https://catalyst.harvard.edu/pdf/regulatory/PaymentGuidance.pdf>
2. Key things for participants to consider before joining a study: <https://www.cff.org/Research/Developing-New-Treatments/Clinical-Trials/What-to-Consider-When-Joining-a-Clinical-Trial/Time-Travel-Expenses-and-Other-Logistics/>
3. Czarny MJ, Kass NE, Flexner C, Carson KA, Myers RK, Fuchs EJ. Payment to healthy volunteers in clinical research: the research subject's perspective. Clin Pharmacol Ther. 2010 Mar;87(3):286-93. doi: 10.1038/clpt.2009.222. Epub 2010 Jan 20. PMID: 20090675; PMCID: PMC2946170.
4. Millum J, Garnett M. How Payment for Research Participation Can Be Coercive. Am J Bioeth. 2019 Sep;19(9):21-31. doi: 10.1080/15265161.2019.1630497. PMID: 31419191.
5. Phillips TB. A Living Wage For Research Subjects. J Law Med Ethics. 2011 Summer;39(2):243-53. doi: 10.1111/j.1748-720X.2011.00593.x. PMID: 21561519.
6. US Bureau of Labor Statistics Wage Estimates: <https://www.bls.gov/oes/current/oes_in.htm>
7. Vulnerable Populations: <https://grants.nih.gov/policy/humansubjects/policies-and-regulations/vulnerable-populations.htm>