

Northwestern University IRB Guidance on Research Participant Payments

Introduction – Ethical Issues Pertaining to Payment for Research Participation

Participant payment raises ethical issues pertaining to the requirement for voluntary research participation and the individual's ability to make informed choices about research that are based on the risks and benefits of participation, not solely on financial incentives. Federal regulations and commentaries offer guidance about participant payments but do not set strict limits on payment amounts. This guidance describes the types of payments made to research participants and acceptable payment practices.

The IRB is responsible for review and approval of payment arrangements offered to a participant or family for research participation, as part of the IRB's review of the research study documents. Per guidance from both the HHS Office of Human Research Protections and the Food and Drug Administration (FDA), the IRB should assure that proposed payments do not create an undue influence to participate in research. Undue influence occurs when an offer of an excessive reward distorts decision-making, compromising a potential participant's evaluation of risks or affecting the voluntariness of the individual's choice.¹ FDA has stated, "In contrast to payment for participation, FDA does not consider reimbursement for travel expenses to and from the clinical trial site and associates costs such as airfare, parking, and lodging to raise issues regarding undue influence." FDA Information Sheet, Payment and Reimbursement to Research Subjects, January 2018.

Being motivated by payment to participate in research, even if someone would not have made the choice to participate in the absence of payment, is not by itself ethically concerning – the problem arises when payments lead to distorted decision-making that puts the validity and voluntariness of informed consent in doubt. A favorable risk-benefit determination by the IRB diminishes the potential negative impact of payments distorting decision-making by ensuring that participation is generally reasonable for the study population.

Definitions

Compensation: A predetermined payment provided to research participants for the time, effort, inconvenience, and general expense of participating in a research activity. Compensation is considered taxable income.

Reimbursement: A payment to research participants/families for direct, out-of-pocket research-related expenses based on actual expenses (e.g., transportation, parking, lodging, meals, childcare, etc.) incurred as a result of their participation in research. The actual expenses must be based upon (1) receipts (or other valid, acceptable documentation) that are collected and submitted for the exact

¹ The concepts of coercion and undue influence are often conflated. Coercion occurs when an intentional threat of harm is used to influence decision-making. Coercion always involves a threat of something undesirable, while undue influence involves an offer of something desirable that distorts decision-making. The main ethical and regulatory concern with payments is the risk of undue influence, not coercion.

amount as the original expense, or (2) allowances for lodging or meals and incidental expenses up to the IRS-set per diem rates.

Tokens of Appreciation: Tokens of appreciation are small gifts of appreciation that include tangible items of nominal value such as T-shirts, mugs, calendars, books, stuffed animal, tote bag, etc.

Payment Procedures

Permissible Payment Amounts

There is no hard and fast rule about how much participants should be paid for research participation. Payment to compensate for time, effort and inconvenience of research participation is permissible, provided that it does not represent an undue inducement.

In international research settings, payment amounts and methods must take into account the sociocultural conditions and circumstances of the countries and regions where the research will take place.

For research that will enroll children as participants, the IRB should consider whether the payment amount could create pressures within the parent/guardian-child relationship, with children experiencing pressure from parents/guardians to participate or continue participating in a study due to the payments involved.

Permissible Forms of Payment

Investigators can pay participants by various methods including cash, check, or gift card. For details on which payment methods are allowed under which circumstances, see [NU Office of Financial Operations Policy on Research Participant Payments](#). If you are unsure whether the payment method you propose to use in your research study is permitted by NU, please check with NU's Office of Financial Operations.

When determining the payment method, consider factors such as:

The characteristics of the participant population (Are they likely to have bank accounts? Can they easily cash checks? Could carrying cash home from the research site pose risks for participants?)

Study procedures (for example, internet surveys should not require a face-to-face interaction for the participant to receive payment)

Non-Permissible Forms of Payment

The IRB does not permit the following forms of payment/compensation or financial arrangements:

1. Use of finders' fees, recruitment bonuses or incentives. Referral payments to study participants may be acceptable if approved by the IRB (for example, in studies using respondent driven sampling (a type of snowball sampling)).
2. A coupon good for a discount on the purchase price of the product once it has been approved for marketing.

3. Providing participants with a private industry sponsor’s advertising materials (e.g., items containing the sponsor’s name, logo, commercially identifiable marking or drug name) as a method of payment.

Timing and Pro-Rating of Payments

The timing of payments to participants impacts considerations of undue influence. FDA has stated, “Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. ... While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable...” FDA Information Sheet, Payment and Reimbursement to Research Subjects, January 2018. For studies of considerable duration or that involve multiple interactions or interventions, the HHS Office of Human Research Protections recommends that payment be prorated rather than delayed until study completion, because the latter could unduly influence a participant’s decision to exercise his or her right to withdraw at any time. For example, if the study is conducted over a period of 6 months, there might be a monthly or bi-monthly payment. Or, if the study involves 12 sessions, there might be payment after every two sessions.

For studies lasting only a few days, a single payment date at the end of the study, even to participants who had withdrawn before that date, is acceptable.

Investigator Responsibilities

The investigator must include information in the IRB protocol and informed consent documents describing when and how the proposed payments will be made to participants. Payment cannot be described as a benefit of research participation in the consent documents. Any payment amounts or bonus payments that could vary based on the participant’s performance and decision-making or the performance of a group of participants must be clearly explained in the protocol and consent information, including the range of possible payment amounts. A change in the amount or terms of compensation during the course of the research is considered a protocol modification and must be submitted to the IRB for review and approval.

If a payment method has restrictions and conditions on its use (e.g., cannot be used to buy certain types of items or services, must be activated within 90 days), or fees associated with use or lack of use, that information should be provided to participants either in the consent form or in a separate form provided to participants – it is up to the investigator whether to include details about payment restrictions and conditions in the consent information or in a separate form.

When payment to an individual could exceed \$600 in a calendar year, the study team must disclose to participants that Northwestern University will be required to issue IRS Form 1099 to the research participant. If a research participant is an NU employee, the study team should explain that NU policy requires payment be made via NU payroll. As with all data related to research participation, it is very important to have appropriate procedures in place to protect the confidentiality of research participant information that is collected for payment purposes.

The protocol and informed consent document must fully disclose:

- to whom payments will be made (in studies enrolling children, be clear whether payments will be made to parent/guardian, the child, or both)

- the form of payment (e.g., cash, gift card, check, etc.),
- when and how the payment will be provided to each participant (e.g., sent via mail or email, cash provided at last study visit)
- the amount of payment, including any pro-rating of payments and any completion bonuses
- whether payment will differ for different groups of participants
- the conditions under which a participant would receive partial or no payment (e.g., what will happen if he or she withdraws part way through the research or the investigator removes a participant from the study for medical or noncompliance reasons).

The timing of payments should be clearly explained (will participants be paid immediately upon study completion or after a certain time period). For example:

Visit Number	Procedures	Compensation
1	In person visit, 30 minutes, blood draw and survey	\$25 gift card upon completion

If proposing to use a drawing (sometimes referred to as a lottery or raffle) as a means of providing research participant compensation, the protocol and consent document must include the following information:

- Amount and total number of payments to be awarded
- Odds of winning, if known
- Approximate timing of the drawing
- How participants who are awarded will be notified

NOTE: State laws impact the use of lotteries, raffles, and drawings – if you will be doing research in states other than Illinois, you need to check whether a lottery format is permissible under the laws of the jurisdictions where the research will occur.

For Further Reading:

Paying Research Participants: Ethical Guidance for IRBs and Investigators, Harvard Catalyst Regulatory Foundations, Ethics, & Law Program, <https://catalyst.harvard.edu/pdf/regulatory/PaymentGuidance.pdf>