Guidance on Payments to Human Subjects

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Brief Overview

• Important concepts
  • Definitions
  • Protocol and consent considerations

• Ethical considerations
  • Amount of payment
  • Timing and methods of payment
  • Compensation of minors and other vulnerable populations
Definitions

• **Compensation**: Payment or non-monetary reward to subjects as remuneration for time and inconvenience of participation in research studies, as well as an incentive to participate.
  - Monetary: Cash, gift cards, vouchers, etc.
  - Non-monetary: Gifts, course credit, extra credit, etc.

• **Undue Influence**: An offer of excessive or inappropriate compensation is made in order to obtain compliance.

• **Coercion**: An overt or implicit threat of harm/negative consequences is intentionally presented by one person to another in order to obtain compliance.
Protocol & Consent Considerations

• Protocol application content must include:
  • Full description of the plan for compensation of subjects
  • Reasoning behind the amount
  • Method of payment
  • Proration & scheduling of payment
  • Other terms of compensation (e.g., what will happen if a subject withdraws)

• All of the above must be included in the consent process
Protocol & Consent Considerations

• Recruiting and advertising materials
  • Disclose possible compensation
  • Payment information should not be any more prominent than other elements (e.g., purpose, procedures, inclusion criteria, and so on)

• *In both the research protocol and the subject consent process, information about compensation should be stated separately from the discussion of benefits of participation.
Important Note:

Under the federal regulations, compensation is NOT considered a benefit to subject participation and is not taken into account when the IRB weighs the risks and benefits of the research.
Amount of Payment

• Compensation should be appropriate for the time and effort subjects devote to participation.

• Level of payment should not be high enough to cause subjects to accept risks that they would not otherwise accept or participate in activities to which they would otherwise object to based on personal values or beliefs.

• Level of payment should not be high enough to induce subjects to lie or conceal information that would disqualify them from the study.
Amount of Payment

• Base payment amount on the acceptable average wage in the location where the research is conducted or for the specific study population.
  • If hourly payments are not feasible, compensation may be task- or procedure-specific

• All subjects completing the same tasks in a single research project should be compensated at equivalent rates.
  • If distinct subject populations are proposed to be compensated at different rates, clear justification for this is required in the protocol (e.g., study to occur at several international sites with different average local wage)
Timing and Methods of Payment

• Making payment conditional on completing a multi-session study could unduly influence a subject’s decision to exercise her/his right to withdraw at any time.

• Recommend prorating payments for time of participation in the study rather than delaying payment until study completion.

• Acceptable to offer a completion bonus (must be reasonable)

• Alternative forms of compensation (gift cards, certificates, other gifts) are acceptable forms of payment and are considered by IRB in the amount of their cash equivalent.
Timing and Methods of Payment

• Compensation may also take the form of a drawing
  • Fair method of selecting winners
  • Consent document must include:
    • A description of the possible prizes
    • The odds of winning
    • Timing of the drawing/payment
    • How subjects will be notified
  • Note: The term “drawing” rather than “lottery” or “raffle” should be used, since the latter terms imply purchase of tickets by participants.
Compensation of Minors and Other Vulnerable Populations

• Federal regulations state that the IRB must determine whether some or all of the subjects are likely to be vulnerable to coercion or undue influence
  • Children
  • Prisoners
  • Pregnant women
  • Mentally disabled persons
  • Economically disadvantaged persons
  • Educationally disadvantaged persons

• Additional safeguards must be included in the study to protect the rights and welfare of these subjects
Compensation of Minors and Other Vulnerable Populations

• Safeguards:
  • Pay special attention to the compensation scheme proposed in the protocol
    • E.g., Researchers involving minors need to consider the ways children of different ages view the value of payment
  • Determine whether payment will be made to the parent(s) or the child, or both
    • Caution: Since parents have the authority to permit a child’s participation in research, excessive payment could cloud the parent’s judgment / exert pressure on child’s decision to participate
  • International research
    • Be mindful of average annual income
    • If compensating using anything other than US dollars, protocol must specify conversion rate
Resources and Guidance

- UIUC OPRS website - https://oprs.research.illinois.edu/guidance-payments-human-subjects
- irb@Illinois.edu
- Phone: 217-333-2670