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Payments to Study Participants

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It would certainly be easier to recruit participants into clinical studies if we could pay them richly for their participation. However, payments that are "too high" constitute undue inducement. Conversely, payments that are "too low" are exploitative. Leaving aside the ethical issues, some research sites prefer stipends that are as large as possible, to maximize participant enrollment. Others prefer stipends that are as small as possible, to minimize expense. The challenge is thus to set payment levels that are "just right": fair, ethical and supportive of the study's enrollment objectives and the site's financial objectives. This article will address payments to subjects in Phase II, III and IV studies. Phase I healthy volunteer studies operate under different ground rules, since there usually are no advantages to the participant other than cash compensation.

Research sites normally pay study subjects for two reasons:

- Stipends for their time, inconvenience, discomfort and/or risk
- Reimbursements for out-of-pocket expenses

Although payments may not be so large as to unduly induce a participant to participate in a study, they may be large enough to make a participant financially whole for their participation. In other words, participation should not cause a participant to lose money. Reimbursement for out-of-pocket expenses is better suited than stipends for this purpose. However, reimbursement for lost income usually is not permitted (or financially feasible) because the amounts could be substantial and vary widely across participants.

Bioethicists and study participants disagree on whether a stipend is a "benefit." From the participant's perspective, it is clearly is a benefit. However, bioethicists exclude stipends from their definition of benefits so informed consent forms can say that the participant will receive no "benefits" from participating in the study. The objective is to minimize undue inducement, but any participant interested in payment will see through the subterfuge and, perhaps, wonder if there are any others. The informed consent form should set forth the conditions, amounts and method of payments in a neutral, non-promotional manner.

Unfortunately, since every study participant is different, it is impossible to set stipend levels that are ethical for every one of them; the best that can be done is something in the middle.[1,2] Although many participants will deny that payments figure into their decision to participate in a clinical trial, some make it very clear that it is important to them. Others care about payment but emphasize motives like medical care and scientific progress. In any case, it is the investigator's responsibility to set payment levels fairly and ethically, subject to IRB approval.

Because setting the level of a stipend is such a subjective task, it is common for sites on the same study to set them at different levels, for example, from $0 to $50 per visit. Stipends are generally larger for visits that are long or involve discomfort, pain or risky procedures. The target population and local cost of living should also be considered. Some sites have a policy of not paying stipends, which addresses the undue inducement issue and avoids a lot of paperwork, but raises the exploitation issue and might interfere with participant enrollment.

Sites often do not pay a stipend for screening visits but might reimburse out-of-pocket, e.g., transportation costs. Paying for screening visits might bring in people with no legitimate interest in, or qualifications for, the study. It is counterproductive to pay for the

screening visit only if the candidate then enrolls in the study, since that would motivate potential participants to falsify information. Nevertheless, stipends for screening visits can be justified if they do not, on their own, provide enough motivation for a potential participant to endure the visit. For example, the screening visit might be very long or involve a significant procedure. Or, two or more screening visits might be required. If it is unusually difficult to entice potential participants to participate in screening visits, that might signal that a stipend is justified or that the site does not have access to the right population or it's an unappealing study that needs to be redesigned or cancelled.

In the case of an unscheduled (extra) visit, there might be a stipend and/or reimbursement, depending on whether the site or participant created the need for the visit. Normally, there are no stipends for "telephone visits."

IRB approval is required to increase a participant's stipend to keep him or her in a study. It may be acceptable to reimburse a participant for legitimate expenses incurred above those specified in the ICF. For example, the participant's car might have broken down, requiring an expensive taxi ride. A participant traveling on holiday may be reimbursed for an airplane ticket to attend a study visit. In both cases, the extra expense benefits the study but, presumably, not the participant. However, the participant may not be reimbursed if he or she benefited by avoiding costs that he or she would have incurred anyway. For example, if a participant buys a one-way ticket for a vacation in Hawaii, the site should not pay for the return ticket.

A participant may be reimbursed for the cost of an unrelated medication required for him or her to continue in a study, even though the participant benefits personally from the medication. However, if the amount of reimbursement is substantial, judgment is required and probably also IRB approval. Such reimbursements relate to the issue of ancillary care — the investigator's obligations to provide treatment to participants for medical conditions unrelated to the study, especially in developing countries where treatment is not otherwise available or affordable.

It is tempting to encourage retention by holding payments back or weighting them toward the end of the study. After all, if a participant drops out, his or her data becomes less valuable or even worthless. However, such a payment pattern would be unethical if it unduly induces the participant to stay in the study. Nevertheless, IRBs have approved such payment schedules, perhaps on the basis that the inducement is not too undue. Paying for compliance may not be unethical, but it might induce a participant to fake it.

Sites may give participants items of modest value like a gift card or a sandwich that are not covered by the informed consent form. Trivial gifts seem acceptable, but IRBs may not agree — it is now beyond the pale for pharmaceutical sales reps to give physicians free pens. Handing out free samples from the drug cabinet is likely to have significant benefit to the participant, so must be clearly dissociated from any study-related incentive without IRB approval.

The site should obtain a W-9 tax form from each participant, even if the amount paid is less than the $600 calendar year threshold that requires the site to file a 1099 tax report. There are two reasons: First, the participant might participate in another study or receive some other payment from the site that, in combination, exceeds $600. Second, the participant should clearly understand that study payments are taxable income, despite the service the participant does for society. The participant should report study payments of any amount on his or her tax returns, with deductions for related expenses like bus fare. The site might want to inform participants if its policy is to file 1099 tax reports even if the amount is under the $600 threshold.

Study sponsors typically do not reimburse sites for the cost of *processing* payments to participants. The labor cost of processing a check at many research sites far exceeds the amount of the check. Fortunately, services are now available that use payment cards to streamline participant payments and generate reports for accounting purposes.

Whenever money is involved, documentation (i.e., receipts) is essential. Study personnel should never write a personal check to a participant. If the accounting department determines that a check has not been cashed after three months or so, the study coordinator should attempt to contact the participant, confirm his or her mailing address, and determine what happened to the check. If a check has not cleared within a few months more, state laws for unclaimed property apply.

References

1. "Much Ado about Subject Compensation," Norman Goldfarb, Journal of Clinical Research Best Practices, September 2008.
2. "Ten Subject Stipend Issues," David Vulcano, Journal of Clinical Research Best Practices, March 2014.

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