

Compensation to Research Subjects

Payment to research subjects is not considered a benefit. Rather, it should be considered compensation for time and inconvenience. When the size of payment to subjects is disproportional, subjects may be unduly influenced to assume risks that they would not otherwise be willing to assume. Reimbursement for expenses incurred as a result of research participation, such as taxi fare, other travel expenses, parking, babysitting fees, or meals, should be designed to offset actual anticipated expenses so as not to create an undue inducement.

A summary of the amount of payment or types of compensation and the proposed method and timing of disbursement should be described to the Institutional Review Board (IRB) at the time of initial review to assure that neither are coercive or present undue influence. Compensation may be monetary or may be in another form, such as a gift card.

Non-permissible forms of payment

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

- Lottery or prize drawings for individuals who participate in research
- Use of finders' fees, recruitment bonuses, or incentives for those who refer prospective subjects
- Bonus payments designed to accelerate recruitment that are dependent on the rate of enrollment

Timing of compensation

Payment/compensation should accrue as the study progresses and not be contingent upon the subject completing the entire study, unless the study has a short duration. In a study lasting only a few days, it may be permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date. For longer studies, payments may be allocated as the subject completes certain study time points or milestones.

Completion payments

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, providing that such incentive is not coercive. The IRB should determine that the amount paid for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.

Disclosure of payments

All information concerning payment, including the form, amount, and schedule of payments, should be set forth in the informed consent document. Payments or compensation should not be listed as a benefit.

Compensation to children

Appreciation gifts for research participation are essentially bonuses to thank the child for their participation. These should be limited to no more than items of token value such as T-shirts, books, stuffed animals, gift cards, etc.

Alterations in payments

Any alterations in subject payments or liberalization of the payment schedule must be reported to the IRB as an amendment prior to implementation.

Reporting payments to the Accounting Department and the IRB

If the subject will be paid by Woman's Hospital, the name and Social Security number must be released to the accounting department at Woman's to process. The collection and release of this information must be addressed in the informed consent process and in the authorization form so that is clear to the subject that his or her identity will be released for the purpose of payment and reporting.

In addition, the Internal Revenue Service requires that whoever is paying the subjects for their participation report payments in excess of \$600 per calendar year on Form 1099-Misc. The filing of these forms necessitate that the name and social security number of the subject be collected on a Form W-9 and released to the Accounting Office at Woman's to process. The collection and release of this information must be addressed thoroughly in the informed consent document so that it is clear to the subject that his or her identity will be released for the purpose of payment and reporting.

For example, the consent form may state:

If you complete this research study, you will receive at least \$600 for (state reason). As a result, you must complete a Form W-9 before the research starts. This form will have your name and Social Security number on it. It will be given to Woman's Hospital's Accounting Department. If you get at least \$600 each year from Woman's Hospital, the hospital must report the payment to the Internal Revenue Service (IRS) on Form 1099-Misc. This form tells the IRS that a payment was made to you. It does not say that you were paid for participation in a research study or if it is taxable income to you. You should talk with your tax advisor about the use of this Form 1099-Misc. If you withdraw from the study before you receive at least \$600, a Form 1099-Misc. may not be sent to you. The IRS Forms W-9 or 1099 will not link you to the study. These forms will only indicate that you received payment from Woman's Hospital.)