Guidance: Compensating human subjects for research activities

Overview

The federal regulations that govern human subject research require that researchers seek participants' consent using procedures that minimize the possibility of coercion or undue influence (45 CFR 46.116). Research incentives may limit the ability of the subject to provide truly voluntary, informed consent. Subjects should be able to make informed decisions to participate based on the real risks and benefits of participation, not on compensation. Subject compensation should be equitable, and the confidentiality of information related to payments should be protected. When reviewing research protocols that include subject compensation, the IRB does so guided by these principles. In designing their research and preparing the protocols describing it, investigators should be aware of the related issues discussed below.

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. Compensation can include monetary (cash, gift cards, vouchers, etc.) and/or non-monetary (gifts/promotional items, course credit, extra credit, etc.) remuneration

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Compensation can become problematic when it produces a situation of *undue influence* or of *coercion.* There are two ways in which compensation can be problematic:

- **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 and ethical considerations

The protocol application should fully describe the plan for compensation of subjects as well as the reasoning behind the amount, method of payment, proration and scheduling of payment, and any other terms of compensation -- for example, what happens if a subject withdraws his or her participation. All of this information should be included in the informed consent process. It is also appropriate to disclose possible compensation in recruiting and advertising materials. In general, payment information should not be any more prominent than other elements (e.g., purpose, procedures, inclusion criteria, etc.). In both the research protocol and the subject consent process, information about compensation should be stated separately from the discussion of benefits of participation. *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. The 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 strongly object based on personal values or beliefs. Excessive incentives may also be of concern since they could induce subjects to lie or conceal information that would disqualify them from the study in order to receive payment. This could in turn undermine the scientific integrity of the study or compromise the safety of the subject.

Some researchers may base the payment amount on the acceptable average wage in the location where the research is conducted or for the specific study population. This is often an acceptable level of payment that does not exert undue influence. When hourly payments are not suitable or feasible, compensation may be task- or procedure-specific (for example, some studies pay subjects per sample collection or survey).

If subjects are being asked to undergo a certain amount of risk, discomfort, or inconvenience with no direct benefit, and no compensation of any kind will be offered, the IRB may ask the investigators to justify this. The same is true if it is proposed to compensate subjects at a rate that is substantially lower than average local compensation for such activity, or to compensate subjects in one group less than another. In general, all subjects completing the same tasks in a single research project should be compensated at equivalent rates. In some cases, distinct subject populations may be compensated at different rates, but clear justification for this is needed. For example, a research study with several international sites may have different payment levels depending on the average local wage.

Timing and methods of payments

Consideration should also be given to timing of payments to research participants. Making payment conditional on completing a multi-session study could unduly influence a subject's decision to exercise his/her right to withdraw at any time. For studies that require extended time or multiple interactions/interventions, it is recommended that payment be prorated for the time of participation in the study rather than delayed until study completion.

While total compensation should not be contingent on completion of the entire study, it is acceptable to offer an additional incentive or completion bonus to subjects that remain for the duration of the study. For example, a researcher might offer a small bonus percentage of total compensation if subjects complete all sessions in a study. If offered, these amounts should be reasonable so as not to unduly influence subjects to stay in the study when they otherwise would have withdrawn.

Alternative forms of compensation (such as gift cards, certificates, or other tangible gifts) are acceptable forms of payment and are considered by the IRB in the amount of their cash equivalent. Other online compensation methods (such as through Mechanical Turk or a prepaid online code) may also be used, but researchers using these forms of payment should ensure that the method of payment can be readily used by participants (e.g., the store or outlet is easily accessible, the subject has access to a computer, etc.) and is appropriate to the population.

> ***Note:*** *For clinical trials, FDA guidance prohibits payment in the form of coupons good for a discount on the purchase price of a test article (drug or device) once it has been approved for marketing.*

Compensation can also take the form of being entered in a drawing. If using a drawing, researchers should ensure that there is a fair method of selecting winners and the consent document must include: a description of the possible prizes, the odds of winning, the timing of the drawing/payment, and how subjects will be notified. When it is not possible to calculate the odds of winning, the reasoning behind this should be included in the protocol and consent form. 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 stipulate that the IRB must determine whether "some or all of the subjects are likely to be vulnerable to coercion or *undue influence*, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects" (45 CFR 46.111 (b)).

Researchers including such vulnerable populations should pay special attention to the compensation scheme proposed in the protocol and subjects' economic status and resources. For example, researchers involving minors as participants will need to consider the ways children of different ages view the value of payment and ensure that the amount and method is age-appropriate and does not present undue influence. For younger children, a small gift/toy may be suitable, but for older adolescents/teens, a gift card or other form of payment may be more appropriate.

In addition, researchers should consider whether payment will be made to the parent(s) or the child, or both. Parents may receive compensation to defray expenses/inconvenience associated with their child's participation in the research. However, *caution should be used*: because parents have the authority to permit a child's participation in research, an excessive payment could cloud the parent's judgment or cause the parent to exert pressure on the child's decision to participate, negatively impacting the rights and welfare of these subjects.

International research sites

Research conducted in international locations involves further considerations. Researchers should be mindful of average annual income of households in the research site and determine whether or not the compensation they are providing may be construed as coercive or unduly influential of subjects' decisions to participate in the study. If compensation will be provided in anything other than American dollars, the protocol should specify the conversion rate and the consent process should communicate the correct currency of compensation.

Confidential/anonymous study subjects

if the payment is to a participant of a human subjects research study and the IRB has approved a waiver of signed consent pursuant to 45 CRF 46.117(c) (1) (confidential/anonymous waiver) or the study is covered by an IRB verification of confidential nature form, incentive payments to anonymous study subjects should not be issued via check; instead, these incentives should be paid in cash, gift cards, and/or tangible goods of value. Please contact Research Administration to obtain instructions for properly maintaining records for payments to confidential study subjects.

Consent form documents

The consent form should clearly specify the amount participants will be compensated, if payments will be pro-rated, the form in which compensation will be provided (cash, gift card, check, etc.), and when participants can expect to receive their compensation.

The protocol submitted to the IRB must describe any information collected from research subjects for accounting purposes (e.g., name, address, social security number, etc.). For projects that involve collection of SSNs, this should be explained in the protocol. The protocol should indicate that these data will be collected separately from the research records and should describe the security measures that will be used to protect subject confidentiality. In addition, the consent process should communicate to subjects that they will be asked for their SSNs, why this information will be collected, and how it will be protected.

Note: Subjects may incur costs as a result of study participation (e.g., parking and transportation costs, meals, etc.). When researchers cover the expenses they are considered reimbursements and should be differentiated from compensation in the study protocol.

U.S. Tax laws

Payments are subject to U.S. tax laws. The IRS treats payments for participant costs, whether in cash, check, gift card, or in-kind items (books, DVDs, etc.) as taxable income to the recipient. This means the recipient is responsible for reporting the payment when he or she files a personal tax return at the end of the year. Northeastern University is required by IRS regulations to issue Form 1099-MISC for all US resident non-employees paid $600 or more in a calendar year. Any payments to non-resident aliens, regardless of amount, are subject to 30% automatic withholding tax unless the non-resident payee is claiming a tax treaty benefit, such as a reduced withholding rate or exemption, by submitting a Foreign National Information Form ("FNIF") to Northeastern (Note: please request FNIF from the Payroll Department: HRM_payroll@northeastern.edu). Payments to foreign nationals are reported on Form 1042-S.

Payments of less than $100 may be made via cash, gift cards/certificates, or non-monetary items of value. A participant receiving incentive or support costs of less than one-hundred dollars is not required to provide his/her personal information (e.g., SSN/ITIN), unless the Principal Investigator reasonably expects that the participant will receive aggregate payments that will equal $600.00 or more in a calendar year in which case the payment should be made via check.

Foreign nationals may receive payments in the U.S. for participating in research or other sponsored activities only if authorized by their sponsoring agencies. Note: A Northeastern sponsored visa does NOT necessarily include such authorization. If a foreign national does not have and cannot obtain such authorization from his or her sponsoring agency, the foreign national cannot be paid for participating in the project.

It is the responsibility of the PI to maintain accurate payment records as good research practice. In the event of an IRS or sponsored programs audit, it is the responsibility of the PI/department and the Office of Finance to provide all required supporting documentation for all payments

Note: Refer to Northeastern University's Research and Sponsored Programs Participant Payment Guidance for further information on the compensation process and reporting requirements.