#### **Research Subjects Review Board**



## **GUIDELINE FOR SUBJECT PAYMENT**

OHSP Policy 703 Recruitment and Subject Payment outlines the requirements for research subject recruitment and methods of subject payment. This guideline provides additional information regarding subject payments (monetary or non-monetary) as part of the recruitment and consenting process.

#### **General Considerations**

- Payment 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.
- Payment in recruitment/advertising materials in general, should not be any more prominent than other elements (e.g., purpose, procedures, inclusion criteria, etc.) or highlighted, bolded or enlarged.
- The protocol should fully describe payment to subjects, as well as the reasoning behind the amount, method, and terms of payment, as applicable. The informed consent document should disclose all information concerning payment, including the total amount, schedule/form of payment, if the payment is considered taxable income, and any plans for prorating payment if a subject withdraws.
- While not considered payment for study participation, the protocol should fully describe reimbursement to subjects, as well as the reasoning behind the amount and process for reimbursement (i.e., reimbursement requires collection of receipts in order to pay the subject back the amount incurred). The informed consent document should disclose all information concerning reimbursement, including what costs will be reimbursed and the process and timeline for getting reimbursed.
- Any changes to the payment or reimbursement information as initially approved by the RSRB must be submitted as an amendment to the RSRB prior to implementation.

**Undue Influence**: An offer of excessive or inappropriate payment is made in order to obtain compliance. **For example**, a researcher might offer hundreds of dollars to subjects for one-day participation in a study to test the effects of an investigational drug with potentially serious side effects. Because the amount of payment could induce subjects to participate against their better judgment, this offer might present undue influence.

**Coercion:** An overt or implicit threat of harm or negative consequences is intentionally presented by one person to another in order to obtain compliance. For example, an instructor might tell prospective subjects in a class that they will lose grade points if they do not participate in the research – this would be coercive.

Payment for research is not coercive in and of itself, since it does not involve a threat of harm. However, payments can create potentially coercive situations, as when a third party is paid for another subject's participation, and that third party can exert coercion over the subject in order to obtain payment. For example, payment to a parent for a child's participation.

### **Ethical Considerations**

**Amount of payment:** Payment 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 might not otherwise accept or participate in activities to which they would otherwise strongly object based on personal values or beliefs. On the other hand, if subjects are being asked to undergo a certain amount of risk or discomfort/inconvenience with no direct benefit, and no compensation of any kind will be offered, the RSRB may ask the investigators to justify this.

**Timing:** Consideration should also be given to the timing of payment. 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.

**Study Completion Bonus:** While total payment should not be contingent on completion of the entire study, it is acceptable to offer an additional 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.

**Forms of Payment:** Alternative forms of payment (e.g., gift cards, gift certificates, or other tangible gifts) are acceptable forms of payment and are considered by the RSRB in the amount of their cash equivalent. Other online payment schemes (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 individuals (e.g., the store or outlet is easily accessible), is appropriate to the population, and maintains subject privacy. **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.

**Student Population**: For studies involving students, class credit or extra credit may be offered as compensation. However, the students must be provided with alternate, equitable ways to earn these credits if they decide not to participate in research (e.g., participation in another study, writing assignment).

### Payment to Minors and other Vulnerable Populations:\*

Researchers including vulnerable populations should pay special attention to the payment 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), the child, or both. Parents may receive payment or reimbursements 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. The RSRB will review, on a protocol-by-protocol basis, the appropriateness of payment proposed for studies involving minors.

# Lotteries, Raffles, and Drawings

**General information:** When proposing to offer a research-related drawing as a form of payment, researchers should be aware of the various federal guidelines including IRS rules, State of New York laws, and other statutes that apply to lotteries, and should keep these in mind to minimize the likelihood of triggering legal issues.

Researchers should use the term "drawing" rather than "lottery" or "raffle," since the latter terms imply purchase of tickets by subjects.

The protocol and consent document(s) should also include the following information:

- Description of the prizes, including estimated value, and the total number of prizes to be awarded.
- The odds of winning a prize, if known, or explanatory language such as, "For any drawing, the odds of winning a prize depend on how many people are entered in the drawing. As we do not know how many people will participate in this study-related drawing, we cannot predict what will be the odds of winning a prize."
- The approximate timing of the drawing (e.g., month/year).
- How the winners will be notified.

### IRS Reporting for Payments to Subjects of \$600 or More:

When payment to an individual subject may meet or exceed the amount of \$600 or more in one calendar year, either as a total payment for one study, or as a result of potentially participating in multiple studies that could accrue \$600 or more, the subject must be informed that the amount is considered taxable income. Refer to the "Payments" section of the RSRB Consent Form Template (<u>Biomedical</u> or <u>Non-Biomedical</u>) regarding the standard language that should be included in the consent. In addition, the University's <u>Payments to Research Subjects for Incentives/Participation</u> policy details the responsibilities of the Investigator for reporting certain payment amounts to University finance.

<sup>\*</sup> Federal regulations stipulate that the RSRB must find "when 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)].