UNIVERSITY OF SOUTH ALABAMA

IRB SOP 1203
Compensation / Incentives for Research Participation

Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the review requirements and recommendations for compensation (monetary and non-monetary) of research subjects to help ensure equitable selection of subjects.

Scope

This SOP applies to all research involving human research participants that receive compensation for their participation at University of South Alabama or its affiliate institutions. Federal regulations provide no clear guidance on the level of compensation that should be offered to research subjects. However, the regulations do require that researchers seek consent only under circumstances that minimize the possibility of coercion or undue influence (45 CFR 46.116).

This policy does not apply to compensation of research participants for a research-related injury. Compensation for research participation is distinct from compensation for an injury associated with participation in a research study. See FDA regulation 21 CFR 50 for further information and see the IRB consent templates for required language.

Definitions

Compensation: Payment or non-monetary reward is given to subjects as remuneration for time and inconvenience of participation, as well as an incentive to participate. Compensation can include remuneration that is monetary (cash, gift cards, vouchers, etc.) and/or non-monetary (gifts/promotional items, course credit, extra credit, etc.).

There are two ways in which compensation can be problematic:

Undue influence: An offer of excessive or inappropriate reward so high that were it not for the amount of the influence, the participant would not enter the study, or the participant would withdraw from the study early, given his or her better judgment. For example, a researcher might offer a month's salary to subjects for one-day participation in a study to test the effects of an investigational drug with potentially serious side effects. Because the level of compensation 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. Compensation for research is not coercive in and of itself, since it does not involve a threat of harm. However, compensation 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 or incentives paid to a doctor or nurse for research recruitment could create coercion.

Policy

Investigators often use incentives to enhance research participation to include various methods by offering gift certificates, vouchers, monetary compensation or class "extra credit". The IRB will consider whether paid participants in research are recruited fairly, informed adequately and paid appropriately. Compensating research subjects for their participation is common and generally accepted practice in research. Compensation for participation in research studies is not considered a benefit. Rather, it is considered a recruitment incentive or compensation for time, effort, and/or unreimbursed expenses.

When subjects receive monetary compensation for study participation, any compensation exceeding $600 dollars in a calendar year is subject to record keeping requirements of the State of Alabama and the Internal Revenue Service.

The nature, amount, and method of payment must not constitute undue influence to participation. Thus, compensation should not serve as encouragement for the subject to participate. Both researchers and the IRB should consider if any component of the proposed compensation would be an undue influence, thus undermining the participant's ability to give voluntarily informed consent (45 CFR 46.116). An inducement is undue, as defined in the IRB Guidebook published by the Office of Human Research Protections, if the compensation is so attractive that is can blind prospective subjects to potential risks or impair their ability to exercise proper judgment. Also, undue influence may occur if the participant is prompted to conceal information that would disqualify them from enrolling or continuing in research. The

following items should be taken into consideration, the subjects educational, employment, and medical status, as well as their financial and emotional condition.

Procedures

1.0 IRB review

The IRB determines if the proposed payment or provision of non-monetary incentives is appropriate for the study. The IRB does not have a cap on compensation, however, reviews the amount of compensation dependent on each protocol and the study population recruited, study duration, and study procedures.

1.1 Basic considerations made by the IRB

Regardless of the form of compensation, the basic considerations related to compensation for participation in research remain the same. The IRB will seek to determine and document as appropriate-

- whether subjects are compensated in a fashion that is commensurate with the time and effort required for participation;
- that compensation does not constitute undue inducement;
- compensation is not stated or treated as a research benefit; and
- overall, that compensation arrangements do not adversely influence subjects.

The following information should be disclosed to prospective subjects during the informed consent process and prior to enrollment whenever possible:

- amount of compensation, including the approximate value of non-cash gifts;
- compensation schedule;
- the approximate odds of winning a drawing or raffle;
- any participant requirements to receive compensation;
- conditions under which compensation will be reduced (e.g., early withdrawal, partial); and
- institutional requirements for the researchers to report participant information in order to properly disburse payment

2.0 Reasonable Compensation Guidelines

When research participants are to be given cash compensation for their participation, the total amount and the schedule of payment(s), if applicable, must be included in the consent document. The amount of the compensation must be “reasonable”, (i.e., adequate to offset expenses, such as the participant’s and/or family’s time and travel) and/or appropriate to serve as a modest compensation for participation. The amount should be proportional to the risks of

the study. The amount must not be so out of proportion to the participant's efforts that it seems coercive. If the study involves multiple study visits involving procedures or significant time commitments, then payment must not be contingent upon the participant's completion of the study. That is, partial payments at intervals throughout the study are appropriate. The IRB will judge the appropriateness of the proposed compensation for each protocol as part of its review.

The following ranges of compensation are suggested as guidelines for investigators and reviewers:

Minimally invasive studies:
$5-$50 per study visit: Study visits involving minimally inconvenient or minimally invasive procedures (blood draws, urine specimens, vital signs, x-rays, anthropometry) and/or questionnaire/survey if lengthy. The lower end of the suggested range would apply to study visits with one or only a few such procedures and the top end of the range would apply to study visits that involve many procedures and/or take several hours of the participant's time.

Actual Transportation Costs Regardless of Type of Study:
$10-$50 for transportation to performance sites that are distant from the participant's home. Compensation for actual travel expenses (or similar costs such as childcare) could be offered in addition to compensation to participate in the study procedures.

Moderately, Extremely Invasive or Time-Consuming Study Procedures
$50-$250 per study visit if there are few visits but each of them involves relatively invasive procedures, or extremely long time commitments or inconveniences. Compensation for single-visit studies could fall into this range depending upon the invasiveness of the procedures, length of the time commitment, and/or inconvenience of participation. Compensation in this range could be offered for every day of inpatient studies, but should not exceed the recommended total (below).

Total Compensation for Multiple Visits:
$100-$1000 total for a study involving multiple study visits, depending upon the invasiveness of the procedures, length and number of time commitments, and inconvenience of participation.

The IRS requires that compensation greater than or equal to $600 be reported to the IRS – refer to http://www.irs.gov/pub/irs-pdf/i1099msc.pdf

2.1 Pro-rated payments

The Office of Human Research Protections and the Food and Drug Administration recommends payment be prorated for studies of considerable duration or that involve multiple interactions/interventions for the time of

participation in the study rather than delayed until study completion. The latter could unduly influence a subject's decision to exercise rights to withdraw.

2.2 Timing of Payments

Unless it creates undue inconvenience or a coercive practice, payment to participants who withdraw from the study may be paid at the time the study would have been completed had they not withdrawn. For example, in a study lasting only a few days, it would be permissible to allow a single payment date at the end of the study, even to participants who withdraw before completion. However, for a study lasting several months, it would not be permissible to allow a single payment date. Participants who withdraw before completion of the study should receive accrued compensation in a timely manner.

3.0 Non-monetary incentives and drawings

Typically payments are monetary incentives; however, subjects may be offered other incentives for participation. For example, free medical care, access to programs/services, extra credit are alternative incentives. Potential participants should be informed opting not to participate will not adversely affect their relationship with the institution or provisions for services provided. Compensation may also be provided by entering a drawing. The consent document must include a description of the prize, the odds of winning, the timing of drawing/payment, who will be present during the drawing, and how subjects are to be notified. The term "drawing" rather than "lottery" should be used, as the latter implies purchase of tickets by the participant.

4.0 Course Credit

Investigators must exercise caution to avoid even the appearance of pressuring students in research studies. If students will be offered extra credit as compensation for participation an alternative extra credit option must also be available if study participation is decline. Alternative choices should be comparable in both time and effort of anticipated study participation. Wherever possible, students should be provided with a choice of research opportunities, including those not supervised by the investigator. Course grades should not be based on research participation.

4.1 Considerations for use of research, extra, or course credit as compensation

Researchers are advised to follow the appropriate department's subject pool guidelines and procedures, where available and related to:

- student recruitment and study enrollment;
- the schedule of disbursement and amount of credit;
- appropriate non-research alternatives to study participation; and
- notifying professors about their students' participation in a study.

Students cannot be *required* to participate in research for extra or course credit since any research participation must be voluntary. If extra or course credit is offered for research participation, a comparable non-research alternative must also be discussed in the proposal. The alternative to participating in the research must be comparable to the research participation in time, effort, and amount of credit or fulfillment of course requirements.

The IRB will seek to determine that:

- alternative non-research activities offered for credit are approximately equivalent in time and effort to participating in the research activity;
- if extra or course credit is discussed during recruitment, then that the recruitment material(s) specifies the amount/value and type of credit that may be earned;
- the informed consent materials adequately describe the conditions for earning the credit whether for the research or the alternative activity;
- explain how and when professors will be notified of their students' research participation (when applicable), and
- where research credit is provided as compensation, that the informed consent materials clearly state that research credit is still awarded either as partial or full credit despite partial participation or early withdrawal.

5.0 Vulnerable Populations

Certain individuals, by nature of their age or mental, physical, economic, educational, or other situation, may be more vulnerable to coercion or undue influence than others. At the time of initial review the IRB will consider ethical reasons for including vulnerable subjects in research. The IRB may determine and require that, when appropriate, additional safeguards be put into place for vulnerable subjects, such as those without decision-making capacity.

5.1 Minors

It is generally acceptable to compensate youth (and/or their parents) for their participation in research. When conducting research with minors, researchers should consider the following:

• Because parents have the authority to grant permission for their children to participate in research, compensation may entice a parent to allow their child to participate against the parent’s better judgment, and/or pressure their child to participate in the research. Often, researchers can avoid undue influence of and by the parents by reimbursing them for expenses associated with their child’s research (e.g. transportation to the lab), and offering the child a token of appreciation at the end of the study.

• Compensation must be appropriate for the age and/or developmental stage, and context of the study. For example, a small toy may be appropriate for a young child, while a gift card may be more appropriate for a teenager. Offering cash to youth should be approached with sensitivity to matters such as how the child might view the value of the cash, and whether or not the child's possession of the cash could put them at risk of harm.
• Consideration of allergies, health hazards, and food handling requirements must be made when offering candy or other forms of food.

6.0 Investigator Responsibilities

6.1 Mechanisms for Processing Payments to Subjects

When using funds obtained from University accounts, investigators must account for monies disbursed during the course of a project. This is a necessary component of financial auditing. However, this accounting must be done in a way that participant confidentiality is not compromised. Using any type of identifier will void confidentiality protection mechanisms and possibly contradict what the participant was informed about in the consent document. Each expense should be tracked by participant ID, the amount paid and when payment occurred and retained in the protocol file.

6.2 Requesting Prepaid Visa Cards

The preferred payment method to participants of research studies continues to be payment by check. The USA Business Office compensation policy provides procedures for requesting prepaid visa cards as an alternative method of compensation. Investigators should contact the USA Business Office at 460-6652 to request prior approval and policy/forms for use of prepaid visa cards available via the USA Credit Union.

Regulated Documents

45 CFR 46.111, 45 CFR 46.116
21 CFR 56.111(a)(3), 21 CFR 50.20, 21 CFR 56.111(a)(3)

HISTORY
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