



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 312.61 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

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

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 (hd2 0 0 12 3)

Students cannot be required to participate in research for extra or course credit. If 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:

- o alternative nonresearch activities offered for credit are approximately equivalent in time and effort to participating in the research activity;
- o if extra or course credit is discussed during recruitment, that the recruitment material(s) specifies the amount/value and type of credit that may be earned;
- o the informed consent materials adequately describe the conditions for earning the credit whether for the research or the alternative activity;
- o explain how and when professors will be notified of their students' research participation (when applicable), and
- o 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, as those without decisionmaking 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 mechanism 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 is the use of a prepaid Visa card.