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 participants 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. This includes pre-determined or set monetary or non-monetary compensation.

This policy does not apply to research compensation provided to participants in the form of reimbursements for actual expenses. Reimbursements can include actual mileage, meals, hotel, or other out-of-pocket costs related to participation in the research. Reimbursement often requires receipts as proof of expenditure.

This policy also 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.

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).

Definitions

Compensation: Payment or non-monetary reward given to research participants 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.).

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. For example, a researcher might offer a month's salary 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 individuals 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 participants 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 individual's participation, and that third party can exert coercion over the participant 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

Compensating individuals for their participation in research is a common and generally accepted practice. Researchers may use compensation or incentives to encourage or enhance participation. Various methods may be used, including offering gift certificates, vouchers, monetary compensation, access to programs/services, small tokens of appreciation, class "extra credit," etc.

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. Compensation should not serve as encouragement for the individual to participate.

The IRB will consider whether paid participants in research are recruited fairly, informed adequately and paid appropriately. Both researchers and the IRB should consider if any component of the proposed compensation, including the nature, amount, and method of payment, would constitute coercion or undue influence to participation. Compensation which is coercive or presents undue influence undermines participant's ability to give voluntarily informed consent (45 CFR 46.116). An inducement is undue if the compensation is so attractive that it can blind prospective participants to potential risks or impair their ability to exercise proper judgment. Undue influence may also occur if the participant is prompted to conceal information that would disqualify them from enrolling or continuing in research. The

participant's educational, employment, and medical status, as well as their financial and emotional condition must be taken into consideration when evaluating research compensation for undue influence.

When participants receive monetary compensation for study participation, any compensation exceeding $2000 dollars in a calendar year is subject to record keeping requirements of the State of Alabama and the Internal Revenue Service (IRS).

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 participants are compensated in a fashion that is commensurate with the time and effort required for participation;
- that compensation does not constitute undue influence;
- that the method of compensation is not coercive;
- 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 participants 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); 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 monetary 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 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 $2000 be reported to the IRS – refer to https://www.irs.gov/forms-pubs/about-form-1099-misc

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 participant's decision to exercise their right 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

Participants may be offered non-monetary incentives for participation. Alternative incentives may include free or reduced medical care, access to programs/services, class extra credit, small gifts or tokens of appreciation, etc. Potential participants should be informed opting to not 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 participants 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 coercion for student participation 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 declined. Alternative choices should be comparable in both time and effort. 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 research 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, 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 participants in research. The IRB may determine and require that, when appropriate, additional safeguards be put into place for vulnerable participants, 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 monetary compensation to youth should be approached with sensitivity to matters such as how the child might view the value of the money and whether or not the child's possession of the money 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

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. This information should be retained in the study file. The Principal Investigator is responsible for maintaining payment logs acknowledging receipt by the participant.

7.0 Methods of Payment

The preferred payment method to participants of research studies is payment by check. If participants will receive over $2,000 in a calendar year, payment by check is required to enable the University to provide this information in the form of a 1099 to the individual for tax reporting.

If payment by gift card is preferred, researchers must follow the USA Business Office participant compensation policy and procedures. Provisions are made for requesting prepaid Visa cards from the USA Credit Union or Tango gift cards. Investigators should contact the USA Procurement Card and Travel Services Office at 251-460-6242 to request prior approval and policy/forms. An IRB approval letter will need to be submitted with the request.

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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