

HRPP GUIDELINE 203

Issuing Office: Office of Research Administration Responsible Officer: Human Protections Administrator Responsible Office: Office of Research Administration Date Issued:

Most Recently Revised: 5-15-07

Guideline Summary-

All human subjects research projects that offer compensation for participation must comply with Purdue University Business Services procedures as well as Institutional Review Board (IRB) review and approval conducted to ensure the compensation amount does not exert undue influence on a subject's decision to participate.

Reason for Guideline

This guideline serves to clarify the criteria required for procuring compensation for human subjects participating in research.

Definitions

Guidelines

The Human Research Protection Program has developed the following guidelines to assist researchers in understanding the procedures required to procure compensation for human subjects participating in research.

It must be noted that compensation for participation in research is not a benefit to the subject. Compensation is primarily a means to offset inconvenience, travel expenses and/or lost revenue due to participation in a research project, however, it may be structured to serve as a recruitment incentive as well.

1. COMPENSATION

In order to comply with Internal Revenue Service (IRS) regulations, Purdue University must report payments to human subjects totaling \$600 or more paid to an individuals during a calendar year. This total is from all payments paid, not just payments associated with an individual research project. To comply this IRS regulation, information needs to be recorded on individuals paid for their participation in a research project. This covers payment via check, cash, cash equivalents, coupons, giveaways, food and drawings. As you develop your IRB application, please consult your department's business office for assistance in understanding the rules associated with these payment methods. Information on this topic can be found at the Business Services website. http://www.purdue.edu/taxes/Human_Subjects/

2. INTERNATIONAL STUDENTS AND NON-RESIDENT ALIENS
Payments to non-resident aliens are subject to withholding and reporting rules that
require tax withholding at the time of payment. This means that although the protocol is

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approved to compensate participants for \$20, non-resident aliens who participate will receive a lower rate because taxes will be deducted. This can create some confusion for the subject participating in the research. It is recommended that investigators be mindful of this issue and alert any potential subject who may be a non-resident alien to the tax withholding requirement. In the event that a research protocol is specifically targeting international students and/or non-resident aliens for recruitment, it would be wise to make this disclosure in the protocol's consent document.

3. EXTRA CREDIT AS COMPENSATION

Extra course credit may be used as a means of compensation for participation as a research subject under certain conditions as listed below.

- a. Any extra credit can be no more than 3% of the course grade.
- b. In classes taught by graduate students, adjunct faculty or lecturers, the supervising faculty member, in concert with the teaching assistant or instructor, must approve this option for the course. In classes where there is no supervising faculty member, the department head, in concert with the instructor, must approve this option for the course. A memo stating the approval should be submitted with the IRB application.
- c. Extra credit options must always include an opportunity to earn the same amount of extra credit in a way that is comparable in time and effort with participation in the study.
- d. A procedure must be developed to ensure the extra credit is awarded after the regular course grades have been computed.
- e. The amount of extra credit should not result in undue influence.

4. APPLYING FOR USE OF COMPENSATION

The IRB reviews both the amount of compensation proposed and the method and timing of disbursement to assure that neither are coercive or present undue influence.

The IRB application must include the following.

- a. The amount, method and terms of compensation.
- b. The amount of compensation must be reasonable and commensurate to the time and effort requested of the subject (e.g., a survey taking a subject 10 minutes to complete would not justify \$50 compensation for the completed survey).
- c. If using a drawing, a verifiable method for determining winners must be established and referenced in the IRB application. Additionally there should be a description of the prize, the odds of winning, and any limitations or restrictions to winning, as well as the date of payoff.
- d. For research studies requiring multiple data collections from an individual subject, credit for payment should accrue as the study progresses and not

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be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn.

- e. While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion (e.g., a balloon payment) as an incentive for completion of the study is acceptable providing that such incentive is not coercive. This amount should be reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.
- f. If the study is such that the investigator might withdraw a subject from the study (for example, not adhering to the research protocol), a description of compensation should be included;
- g. Information concerning payment, including the amount, method, terms and schedule should be set forth in the informed consent document.

Applicable Regulations and Guidelines

45 CFR 46.111, 46.116

21 CFR 50.20, 50.25(a)(1)-(3)

21 CFR 56.111

Food and Drug Administration Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update

Purdue University Business Services Human Subject Policy http://www.purdue.edu/taxes/Human Subjects/

Purdue University Business Services Guidance Sheet for Research Involving Human Subjects http://www.purdue.edu/taxes/Human_Subjects/

Related Documents	
SOP 302 Initial Review	viramenta
SOP 320 Informed Consent Requ Approval	
Date:	Date:
Richard D. Mattes, Ph.D.	Peter E. Dunn, Ph.D.
IRB Chair	Associate Vice President for Research

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