

DHS – Public Health Division

COMPENSATING RESEARCH PARTICIPANTS

The DHS-Public Health Division acknowledges that research depends on the successful recruitment and retention of participants, and as such, researchers will often give money or another form of compensation to persons who participate in a research project. Compensation or incentives for research participation is not a general obligation of the researcher toward the participant; compensation or incentives may be offered in specific studies but are not required. Federal regulations do not specify restrictions on payment of research participants, however, they do indicate that an investigator shall seek consent only under circumstances that provide the potential participant sufficient opportunity to consider whether or not to participate in the research and that minimize the possibility of coercion or undue influence. The policy of the Public Health Division is that compensating research participants or providing an incentive must be nominal in nature (e.g. to compensate for their time, effort, discomfort, inconvenience, expenses, etc.) and shall not be coercive or unduly influence the participants.

The following guidelines will be used by the Public Health IRB (PH IRB) in determining the appropriate use of compensation or incentives and whether the compensation or incentive could be considered coercive or unduly influence the participants involved:

- The form of compensation or incentive being offered (cash, gift card, picture frame, CD, etc).
- Compensation or incentives shall not be considered a benefit, but rather, as reimbursement for time, inconvenience and expenses for participating in the study.
- Judgement of the “reasonableness” of a particular sum of money or other form of payment should be based upon:
 - Complexity of the research as it relates to the inconvenience to the participant;
 - Type and number of procedures to be performed;
 - Time involved;
 - Reimbursement for expenses (e.g. traveling to an appointment, parking fees, etc);
 - Anticipated discomfort or inconvenience of the study; and
 - Subject population.
- The amount or type of compensation or incentive shall not be so large as to constitute a form of undue influence.
- The amount and type of payment will be examined in relation to the risks and burdens of the research. Offers that are too attractive may blind prospective participants to the risks of the study or impair their ability to use proper judgment. In addition, they may prompt research participants to lie or conceal information that, if known, would prevent them from enrolling or continuing to participate in the study.
- Compensation or incentives must be identified during the consent process and documented in the consent form, including the amount, type and schedule of payment(s) if applicable.
- For studies that involve multiple follow-up visits, the participants should be paid in proportion to their time and inconvenience as a result of participation in the research study. Compensation should not be contingent upon completing the study. Investigators may offer an additional incentive if all elements of the research are completed.
- Unless it creates undue inconvenience or a coercive practice, payment to participants 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. For example, in a study lasting only a few days, the PH IRB may find it permissible to allow a single payment date at the end of the study, even to participants who had withdrawn before that date.

- Due to concerns related to fairness and the potential for coercion and undue influence, the PH IRB generally *discourages* the use of a lottery or raffle as a mechanism for participant compensation. The PH IRB will consider such plans for participant compensation on a case-by-case basis, with appropriate justification provided by the investigator.

The PH IRB shall review the type of payment, amount and schedule of payments at the time of initial or expedited review to assure that the compensation is neither coercive nor presents undue influence.

Any proposed alterations to the amount or type of compensation or changes to the payment schedule must be reported to the IRB prior to implementation for review and approval.

Payment to Minors

Because children and adolescents may be more or less prone to being unduly influenced by financial reward, and often have a limited capability to understand the risks and benefits, additional protections may need to be included when offering compensation to minors.

- If compensation is to be provided, the compensation should be given to the participant in a form, manner, and amount appropriate for the age and developmental status of the minor participant
- Recruitment flyers may identify that participants will be compensated for their participation, but should not emphasize the payment or amount to be paid.

Applicable Regulations:

45 CFR 46.116

21 CFR 50.24