

Public Health Division Compensating Research Participants

The Public Health Division acknowledges that some 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 agree to participate. Compensation for research participation is not a general obligation of the researcher toward the participant; they may be offered but are not required. Federal regulations do not specify restrictions on payment to research participants, however, HHS at 45 CFR 46.116 and the FDA at 21 CFR 50.25 do indicate that investigators shall seek consent only under circumstances that provide the potential participant sufficient opportunity to consider whether or not to participate. In accordance with these federal regulations, the Public Health Division policy on compensation is that the provided payment or incentive must be nominal in nature to compensate for the participants' time, effort, discomfort, inconvenience, and expenses. It should not be coercive or result in undue influence.

The following guidelines will be used by the Public Health Institutional Review Board (PH IRB) in determining appropriate use of compensation and whether or not they could be considered coercive or unduly influence the participants involved:

- What is being offered and how much: e.g. cash, gift card, picture frame, CD, etc.
- Purpose: Given as reimbursement for time, inconvenience and/or expenses for an individual's participation in a study. Should not be considered a benefit of participation.
- Reasonableness: Judgement on the particular amount or type of compensation 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;
 - Expected expenses (e.g. traveling to an appointment, parking fees, etc.);
 - Anticipated discomfort or inconvenience of the study; and
 - Subject population.
- Amount and/or type of compensation vs. expected risks/burdens of 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.
- Documentation: Must be identified during the consent process and stated in the consent form, including the amount and/or type and schedule of payment(s), if applicable.
- Fairness: For studies that involve multiple follow-up visits, the participants should be compensated in proportion to their time and inconvenience as a result of participation in each step of the study. It should not be contingent upon completing the entire study, however, investigators may offer additional compensation if all elements of the research are completed.
- Withdrawal provisions: Unless it creates undue inconvenience or a coercive practice, compensation 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, the PH IRB may find it permissible to allow a single compensation date at the end of the study if the study is expected to only last a few days, even to participants who had withdrawn prior to the end-date.

- Lotteries: Due to concerns related to fairness, the PH IRB generally *discourages* lotteries and raffles as mechanisms for participant compensation. Such plans for participant compensation will be considered on a case-by-case basis only with appropriate justification provided by the investigator.

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

Payment to Minors

Because children and adolescents may be more prone to undue influence of financial or other reward and often have a limited capability to understand the risks and benefits of participation in research, additional protections may need to be considered when offering them compensation. The minor-participant should be offered the compensation in a form, manner, and amount appropriate for their age and developmental status. Additionally, although recruitment flyers may identify that compensation will be granted for participation, they should in no way emphasize the type or amount to be given.

Applicable Regulations:

45 CFR 46.116

21 CFR 50.25