

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Payments to Research Subjects	Date Effective 03/16/05	Supercedes P&P dated 11/12/04

BACKGROUND

Federal regulations neither endorse nor prohibit compensation of research subjects. HHS regulations only require that consent be obtained under conditions that minimize coercion or undue influence. FDA regulations require that IRBs review the amount, method and timing of payment to ensure that these are not coercive and do not create undue influence.

JHSPH POLICY AND PROCEDURES

The following guidelines are not meant to endorse or condone payment of subjects. Rather, they provide criteria for determining whether proposed payments meet the standard of being free of coercion or undue influence and suggest strategies to achieve this objective. Special consideration is given to selecting appropriate payment for children and other vulnerable subjects.

Any payment or incentive, whether financial or non-monetary, that is offered for participation should be described in detail in the research plan and explained in the consent documents that are submitted to CHR for review. Details about payments should include the total to be paid for completion of the study, prorating of payments and the payment schedule. CHR considers each proposal for payment of research subjects on a case-by-case basis and reserves the right to require that a monitor observes or supervises subject recruitment to ensure that payment is not coercive.

The following are guidelines to assist investigators to determine whether a proposed payment plan is appropriate and is adequately described:

- Payment must not be coercive or be used as an undue inducement to participate in research.
- The amount of payment may be stated on recruitment flyers but should not be overly emphasized (see [Direct Advertisements](#)).
- The amount paid is not a benefit, but should fairly reflect the time that will be invested by the subjects, the burden that will be imposed upon them by the research procedures, and other inconveniences they may experience as study participants, especially when the study offers little or no prospect of a direct health benefit to the subjects.

- Reimbursement of subject expenses, such as for transportation to the study site, is allowed, but is not considered a payment for participation.
- Payment may be in cash or in kind, such as with food or clothing.
- Payments should be sensitive to local culture and living conditions.
- Payments to persons who fulfill all study requirements may include a small added amount for completion, provided it is not coercive. Subjects who leave a study early, for any reason, should be paid on a reasonable prorated basis to avoid the impression that the investigator is coercing them to continue in the study or is punishing them for dropping out.
- Vulnerability of the study population should be taken into account; including medical, employment and educational status, and financial, emotional and community resources.
- All information concerning payments, including the amount and types of compensation, and the schedule of payments, should be described in the research plan and the consent document.

Payments to Children, Prisoners and Other Vulnerable Populations

Investigators and CHR must weigh especially carefully any payment provided to children, prisoners, and other vulnerable populations to ensure it does not unduly influence their decision to participate in research. Whatever the compensation, it should not outweigh the risks associated with the research and the inconvenience of participation.

Children, especially young children, have limited ability to understand the risks and benefits of research. Because they may be easily influenced by monetary or other forms of payment, care should be taken to ensure the payment does not unduly influence the decision to enroll the child or of the child to give assent. For example, forms of compensation considered “minor” in the US may be viewed as excessive in other populations. Age-appropriate and culturally sensitive forms of compensation should be considered as alternatives to monetary incentives. A small toy, for example, may be appropriate for a very young child. For an older child, an item of clothing or a gift certificate may be suitable. A bar of soap may be considered a luxury in an economically disadvantaged population.

The provision of toys or other tokens to children in school may create jealousy among those who do not participate. T-shirts or other items that display the study name or logo may not be appropriate for studies of a sensitive nature, since public display may label the individual inappropriately.

To avoid possible conflict of interest, parents should *not* be given incentives, monetary or otherwise, to encourage them to give permission for their child to participate in research. They may, however, be compensated for actual costs that they will incur, such as for transportation or lost wages.

Payments of money may easily be an undue influence in certain vulnerable populations, such as injection drug users. Non-monetary forms of payment should be considered.

Paying prisoners the same amount as would be paid to non-prisoners may be unduly influential in a setting where inmates can earn only a small fraction of that amount for any

other “work” activity. On the other hand, paying prisoners a fraction of what would be paid to non-prisoners may be seen as exploitative. One possibility is that investigators would pay prisoners at the same rate as non-prisoners, but the individuals would only receive directly an amount similar to that paid for other prison tasks. The difference could be paid into a general fund to be used, for example, to enhance the wages paid to all prisoners or for educational or recreational purposes that are decided by the prisoners. Alternatively, the difference could be paid to an escrow account to be distributed to the prisoner upon release or to be paid to the prisoner’s family. Some prisons have specific policies and procedures for payments of money to prisoners; these should be determined before submitting a research application to CHR.

DEFINITION

Coercive: an offer one could not refuse; also considered “undue.” [From the DHHS IRB Guidebook]

Undue influence: one that seems excessive, considering the risks, efforts and inconvenience associated with the research, and the population under study.

RESOURCES & REFERENCES

DHHS IRB Guidebook

45 CFR 46.116

FDA 21 CFR 50.20