SOP 2.3.2 **Providing Incentives to Participants**

General Description:

Paying or compensating research subjects in exchange for their participation is a common and generally acceptable practice in research. The Mason IRB considers payment of research subjects to be a recruitment incentive or compensation for time, effort, and/or unreimbursed expenses required of subjects participating in a given research project. ***Payment to research subjects for participation in studies is NOT considered a benefit.***

The nature, amount, and method of payment or other compensation should not constitute undue inducement to participate (i.e., the payment should not serve as excessive encouragement for the subject to volunteer). In development and review of a research study, researchers and the IRB should consider whether any aspect of the proposed compensation would be an undue influence, thus interfering with the potential subjects' ability to give voluntary informed consent (45 CFR 46.116). Taking into consideration the subjects' medical, employment, and educational status, and their financial, emotional and community resources, it should be determined whether the compensation offered for participation in research is appropriate given the research activities in which they will participate.

Non-monetary incentives
Although payments are usually monetary, human research subjects may be offered other rewards in lieu of or in addition to money. No-cost medical care, access to services and programs, extra credit, and provided meals are examples of alternative incentives. Non-monetary incentives can be provided as long as the incentives are not so great as to diminish the voluntariness of consent or impact the potential subject's ability to effectively consider the risks and benefits of research participation. Moreover, it must be clear to subjects that choosing to not participate will not adversely affect an individual's relationship with the institution or its staff or the provision of services in any way (45 CFR 46.116(a)(8)).

Pro-rated Payment
OHRP and FDA recommend that payment be prorated for the time of participation in the study rather than delayed until study completion because the latter may unduly influence a subject's decision to exercise his or her right to withdraw at any time. If participation in the study will take place over multiple visits/sessions, it is suggested to not make payment contingent on the participant's completing the entire study, but instead provide increased payment as the study progresses, prorating the payments based on the number of study visits, or other comparable milestones, completed by the research participant.

Payment to Minors, Parents
Age-appropriate compensation (including small gifts) can be provided to minors involved in research. Parents and guardians may also be provided with an appropriate payment, although it should be considered whether there is a substantial conflict of interest in providing these payments. See SOP 1.4.1. "Research Involving Children" for more information on research involving children.

Payment to Prisoners
Prisoners are considered vulnerable because they are in a restrictive, institutional environment that affords little opportunity for autonomy, earning money, or communicating with outsiders. Any possible advantages or compensation to the prisoner for participation in research, when compared to the general living conditions and opportunities in the prison, must not be so great that they impair the prisoner's ability to evaluate the risks and benefits of the research. The IRB must ultimately consider the amount and mode of compensation to prisoner participants in regards to the unique limits on prisoner autonomy. See SOP 1.4.3 "Research involving prisoners" for more information on research with prisoner populations.

Payment in International Research
The context of the local economy, cultural practices, general living conditions, and opportunity for earnings should be taken into account when the researcher determines the nature, value and method of payment, and to whom it will be provided.

If a person is to be paid in cash or goods at a value that significantly surpasses what would be commonly available in the local community, such payment could constitute undue influence. The researcher should provide a description of the compensation in terms of both US and local currency and describe the payment in relative terms (i.e., payment is equivalent to a day's work, hourly salary, or another local reference).

IRB Review of Payment:

Both researchers and IRBs need to be familiar with the study population and the context of the research in order to make reasonable judgments about how compensation might affect participation. Information submitted to IRBs should include:

- Description of payment
- Nature and value of payment
- Method of payment
- Partial payment for participants who withdraw

This information should be clearly stated both in the IRB protocol as well as the informed consent form. Researchers must inform subjects as precisely as possible about when, how, and what payment for their participation will be made to them. The IRB will determine whether the proposed payment or provision of gifts/tokens to participants is appropriate under the circumstances of the study.

References:

45 CFR 46.116
Human Research Protections Frequent Questions (FAQs); http://answers.hhs.gov/ohrp/questions/7251
45 CFR 46.116(a)(8))
FDA Payment to Research Subjects - Information Sheet

Related Forms, Guidance, and SOPs:

- 1.4.1. Research Involving Children
- 1.4.3. Research involving prisoners
- 2.3.1 Participant Recruitment

Responsibility:

Principal Investigators
Research Team Members
IRB staff
Institutional Review Board

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	06/25/2014
Greg Guagnano	IRB Chairperson	06/25/2014