Department: UAMS Institutional Review Board
Policy Number: 14.2
Section: Recruitment Practices
Effective Date: July 31, 2002
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SUBJECT: Research Participant Payment

POLICY
Compensation or payment to research participants shall be viewed as compensation for time and inconvenience. It shall not be considered a benefit of the research. Participants may also be reimbursed for actual costs associated with participation, such as travel, parking, food, and accommodations. Investigators and the IRB shall develop and review compensation plans with the goal of adequately compensating participants while not unduly influencing the subject's decision to join or to continue in a research study, or to appropriately weigh the research's risks and benefits

DEFINITIONS
Reimbursement – Payments that compensate participants and, if applicable, their Legally Authorized Representatives (LARs) for their direct research-related costs. Normally these payments are based on actual costs documented with receipts, in which case reimbursement amounts may differ among participants. However, a sponsor may choose to reimburse a flat reimbursement cost for all participants, or to make expense reimbursement contingent on the distance the participant must travel to reach the study site.
Compensation – Payments designed to compensate parents and, when applicable, LARs, for the time and inconvenience of research participation. The demands of the research, including but not limited to the number of clinic visits, invasiveness of research procedures, and time spent on research procedures, are to be the foundation of the compensation amount. All participants normally receive the same participation.
Payment – For purposes of this policy, "payment" refers to reimbursement and/or compensation, as described above.

PROCEDURE
A. All study submissions that involve compensating subjects shall fully describe the planned compensation, including the amount, timing, and method of payments.
B. Investigators are to ensure the payment method, e.g. cash, gift card, check, is consistent with institutional policy.
C. Payment of either compensation or reimbursement shall not be contingent upon completion of the entire study. However, payment of a small proportion of compensation as an incentive for completion of the study is acceptable, provided such incentive is not so large as to unduly influence a decision to complete the research.
D. Payments must be pro-rated where appropriate, with compensation accruing with the amount of time and inconvenience in the study.
E. For participants who require the permission of another person to join a research study, such as minor children or the decisionally impaired who cannot provide their own consent, the compensation description must indicate who will receive the payment (the participant or LAR), and the rationale for determining who will get the payment. For example, it may not be appropriate for a minor to receive a gift card for compensation, depending on the age of the minor. Also, if compensation will be provided to the LAR, the investigator must describe, and the IRB will consider, whether the payment may induce the LAR to override the participant's wishes regarding participation. Note that other regulatory considerations also apply when considering the extent to which the non-competent participant's wishes can be respected.
F. The IRB will review the payment amount and the proposed method and timing of disbursement to ensure proportionality with the time and inconvenience involved in study participation. The IRB may request changes in the proposed payment timing or amount.
G. Unless it creates undue inconvenience or a coercive practice, payment to subjects who withdraw early may be paid 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, an IRB may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date.
H. Payments shall be fully described in the informed consent process and in any associated informed consent materials.

I. The IRB will not allow sponsor coupon or other inducement related to a discount on the purchase price of the study product once it has been approved for marketing to be provided to participants.
J. Advertisements may state subjects will be paid or compensated and may include the payment amount, but may not emphasize the payment or its amount by such means as larger or bold type.
K. Any alterations in subject payment or payment schedule must be submitted to the IRB as a modification and approved prior to implementation.

REFERENCES

AAHRPP Elements II.3.C, III.1.E
OHRP Informed Consent FAQs, specifically *When does compensating subjects undermine informed consent or parental permission?*
FDA Information Sheet *Payment and Reimbursement to Research Subjects*
SACHRP Guidance *Addressing Ethical Concerns Regarding Offers of Payment to Research Participants*