Subject: Payments to Research Participants

Definitions:
1. Third-party: Any person or vendor (external to Vanderbilt University or Vanderbilt University Medical Center) who receives payment for providing research-related services and/or products.
2. Research Payments: Cash and non-cash payments for reimbursement of time and expenses associated with participation in research activities.

Policy:
It is the policy of the Human Research Protections Program (HRPP) to review and approve payments to human research participants.

I. The IRB must determine that the risks to research participants are reasonable in relation to the anticipated benefits and that the informed consent document contains an adequate description of the study procedures as well as the risks and benefits. Payment to research participants in studies is not considered a benefit. Rather, it should be considered compensation for time and inconvenience or a recruitment incentive. The amount and schedule of all payments should be presented to the IRB at the time of initial review. The IRB should review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive nor present undue influence.
   A. Timing of Payments. Credit for payment should accrue as the study progresses and not be contingent upon the participant completing the entire study. The participants should be paid in proportion to their time and inconvenience as a result of participation in the research study. Unless it creates undue inconvenience or a coercive practice, payment to participants who withdraw from the study may be paid at the time they would have completed the study (or completed a phase of the study) had they not withdrawn.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 Committee may find it permissible to allow a single payment date at the end of the study, even to participants who had withdrawn before that date.
   B. Completion Bonus. While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable, providing that such incentive is not coercive. The IRB will determine whether the amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
   C. Disclosure of Payments. All information concerning payment, including the amount and schedule of payments should be described in the informed consent document.
   D. Advertisement of Payments. Advertisements may state that participants will be paid or compensated, but should not emphasize the payment or the amount to be paid, by such means as larger or bolded type (See HRPP Policy X.G).

II. Alterations in Payments. Any alterations in research participant payment or liberalization of the payment schedule must be reported to the IRB prior to implementation as an amendment (See HRPP Policy III.J).

III. Reporting Payments to the IRS. The Internal Revenue Service (IRS) requires that VU or VUMC (or whomever is paying the research participants for their participation) report payments in excess
of $600 per calendar year on Form 1099-Misc. The filing of these forms necessitate that the name and social security number of the participant be collected on a Form W-9 and released to the Office of Accounting to process the Form 1099-Misc. The collection and release of this information must be addressed thoroughly in the informed consent document so that it is clear to participants that their identity will be released for the purpose of payment and reporting.

References:
45 CFR 46
21 CFR 50.20