Subject: Procedure for Payment to Research Participants

Procedure:
This procedure provides guidance for payment to research participants under the jurisdiction of the Human Research Protections Program (HRPP).

I. Investigator Responsibilities.
A. The Investigator will provide a detailed description of proposed payments to research participants. This will include timing of payments, pro-rating schedule, payment for participants who withdraw before completion, and completion bonus plans, if applicable. Please note: departmental forms to initiate compensation for participation in research studies do not require IRB review and approval.
B. Any alterations in payments to research participants are to be submitted as an amendment to the IRB prior to implementation (See HRPP Policy III.J).
C. All information concerning payment should be incorporated into the informed consent document using the IRB template. This information should be addressed in the consent template, Item #9 “Compensation for Participation.” Payments are not a benefit and are not to be included in the benefits section of the informed consent document.
D. The Investigator will provide the Office of Accounting the name and social security number of participants who receive payments in excess of the IRB annual reporting threshold per calendar year on Form W-9 for processing the Form 1099-Misc to be forwarded to the IRS.
   1. 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 IRS reporting.
   2. The IRB approved standardized template language will be used to draft the informed consent document. The current template language is located on the HRPP website at http://www.mc.vanderbilt.edu/irb/.

II. IRB Committee Responsibilities.
A. The IRB Committee, the Chairperson or designated Committee Member will review the planned research activities to determine that the risks to 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.
B. The IRB will review the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence.
C. The IRB must assure the entire payment is not contingent upon the participant completing the entire study, unless the study is of short duration or only a one-time procedure. Payment should accrue as the study progresses.
D. The IRB should determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly influence participants to stay in the study when they would otherwise have withdrawn.
E. The IRB will review advertisements to assure the advertisements are not coercive or present undue influence and do not emphasize the payment or the amount to be paid, by such means as larger or bolded type (See HRPP Policy X.G.).
F. Social security numbers must be collected from participants given any form of compensation for participation. Waivers may be considered on a case by case basis for the collection of social security numbers where the documentation of such carries the potential to place a participant at risk and the amount is small enough that reaching the IRS annual reporting threshold within a given year is highly improbable.

G. The IRB must determine if payment made directly to a minor is appropriate or inappropriate by carrying the risk of undue inducement.

III. Regulatory Compliance Analyst Responsibilities.

A. The RCA will conduct a pre-review of the IRB application, the informed consent documents, and advertisements submitted with a new study application to determine that the method of payment for participation in research is consistent with HRPP policy, as well as ethical standards.

B. If additional information regarding payments to participants is needed, the RCA will contact the Investigator and request the additional information.