Policy Number: 21
Title: Participant Compensation
Date of Last Revision: 08/10/05, 09/27/10, 01/24/11

Policy:
It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) 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, effort and inconvenience. The amount and schedule of all payments should be presented to the IRB at the time of initial review or via a modification request.

A. The IRB should review the amount of payment and the proposed method and timing of disbursement to assure that neither is coercive nor presents undue influence.

B. 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the study may be paid at the time they would have completed the study (or completed a phase of the study) had they not withdrawn.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Committee may find it permissible to allow a single payment date at the end of the study, even to participants who had withdrawn before that date. In general, a single payment date is not permissible especially for longitudinal studies lasting several months. Moreover, participants who withdraw before completion of a longitudinal study should receive accrued compensation in a timely manner.

C. 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is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.

D. Disclosure of Payments. All information concerning payment, including the amount and schedule of payments should be described in the informed consent document.

E. Advertisement of Payments. Advertisements may state that participants will be paid or compensated, but the payment or the amount to be paid should not be over-emphasized (*See* IRB Policy 22)

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 a modification request (*See* IRB Policy 17)

III. Reporting Payments to the IRS - The Internal Revenue Service (IRS) requires that UC Irvine (or whomever is paying the research participants for their participation) report payments in excess of

IV. Use of Sponsor Coupons - The use of sponsor coupons, as a form of participant compensation, good for a discount on the purchase price of the product once it has been approved for marketing is prohibited.

V. When following a Department of Defense Addendum

A. When research involves U.S. military personnel, policies and procedures require limitations on dual compensation as follows:

1. Prohibit an individual from receiving pay from more than one position for more than 40 hours of work in one calendar week;
2. Prohibit an individual from receiving pay of compensation for research during duty hours. U.S. Military personnel may be compensated for research if the participant is involved in the research while not on duty.
3. The policy includes temporary, part-time, and intermittent appointments.

References:

45 CFR 46
21 CFR 50.20
U.S. Food and Drug Administration Information Sheets: "Guidance for Institutional Review Boards and Clinical Investigators," 1998 Update
IRB Management and Function; Amdur, R. and Bankert, E.; 2002 Jones and Bartlett Publishers, Inc.
DoDD: Dual Compensation Act, 24 U.S.C. 301

Procedure Number: 21.A
Title: Procedure for Participant Compensation

Procedure:
This procedure provides guidance for payment to research participants under the jurisdiction of the UC Irvine (UCI) Institutional Review Board (IRB).

I. Lead Researcher (LR) Responsibilities
- A. The LR will provide a detailed description of proposed payments to research participants in the IRB Protocol Narrative. This will include timing of payments, pro-rating schedule, payment for participants who withdraw before completion, and completion bonus plans, if applicable.
- B. Any alterations in payments to research participants are to be submitted as a modification request to the IRB prior to implementation (*See* IRB Policy 17)
- C. All information concerning payment should be incorporated into the informed consent document using the applicable IRB template. This information should be addressed in the consent template, under the heading, "Compensation, Costs and Reimbursement." Payments are not a benefit and are not to be included in the benefits section of the informed consent document.
- D. The LR should provide the Office of Accounting and Fiscal Services the name and social security number of participants who receive payments in excess of $600 per calendar year preferably 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.

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 nor 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 over-emphasize the payment or the amount to be paid. (*See* IRB Policy 22)
- F. The IRB must determine if payment made directly to a child is appropriate or inappropriate by carrying the risk of undue inducement.

III. IRB Analyst or Higher Responsibilities
- A. The Analyst will conduct a pre-review of the IRB protocol narrative, the informed consent documents, and advertisements submitted with a new IRB application to determine that

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