OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #503.4 Revision 4	**TITLE: Compensating Participants**	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature	Date 3/1/2019
Approved By: IRB Chair	Signature	Date 3/1/2019

PURPOSE

To describe the policy related to compensation for participation in human research under the oversight of the Institutional Review Board (IRB).

REVISIONS FROM PREVIOUS VERSION

Update records retention to 3 years, adding FDA reference, and administrative corrections

POLICY

It is IRB policy to evaluate for approval all planned incentive and compensation components of human research projects. Payments to research participants are of two types: mild incentives involving nominal value, and compensation that is calculated based on total time, effort, costs and inconvenience involved in participating. The IRB will consider the amount and schedule of incentives and compensation in assessing the appearance or fact of undue influence or coercion. In addition, the IRB will consider the financial status of participants receiving the payments to avoid undue influence and may result in a variance from the standard compensation rate. All information concerning incentives should be included in the protocol and informed consent document, including amount, method and timing of disbursement.

RESPONSIBILITIES

Execution of SOP: Researchers, IRB.

PROCEDURE

Accounting

1. According to the federal tax code, payment for purposes of research participation by cash, check, money order or gift card in the amount of $600 or more per year is taxable income. As such, each participant receiving compensation to participate in a project is requested to sign Participant Receipt Form (for less than $600) as per UNM Policy 2480: Incentives for Program Participants. If the incentive is less than $600 per calendar year, the receipt is for internal department use. If the incentive(s) are $600 or more, the researcher is required to complete the Participant Receipt Form (for more than $600) and forward it as directed on the form within two weeks after the threshold is met. This form requires collection of an individual's social security number. This may reduce the privacy protections that may be assured to participants as a result. In these cases participants must be informed that their names and social security number will be released for purposes of providing payment and recording state and federal tax information.
2. All records of payments to participants must be securely kept for a minimum of three (3) years after the close of the project.
3. Participants are NOT required to provide their names or social security numbers when participating in a project when the IRB has approved a waiver of a signed consent according to 45 CFR 46.117(c)

or 21 CFR 56.109(c) or the researcher has obtained a Certificate of Confidentiality issued by the NIH. Participants may use a checkmark instead of a signature to indicate confidential receipt of the incentive, or the principal investigator may sign to verify disbursement of incentives.

Incentives/Compensation

1. Incentives may be cash (checks, money orders, gift cards) or gifts of nominal value (e.g. UNM merchandise) that are not, in and of themselves, anticipated to influence an individual to participate in the research against their best interests. If incentives are mentioned in any recruiting materials for the project, the procedures should also be briefly described. Incentives should also be clearly described in the consent document, if applicable.
2. Compensation typically is made in the form of cash or cash equivalent gifts (i.e. retail merchant gift cards). Compensation payments must be described in detail in the consent document, including pro-rated payment schedules if the participant withdraws before the completion of the project. Any researcher-initiated changes concerning payments, including changes to the payment schedule, must be approved by the IRB prior to implementation.
3. The IRB reviews compensation to ensure that payment is not contingent upon the participant completing the entire project and that any amount paid as a bonus for completion is reasonable and does not unduly induce participants to stay in the project until completion.

Course Credit

1. If course credit or extra credit is offered to a student population, the researcher must offer a non-research activity that is equivalent effort and time/duration to participation.

Research Lotteries/Raffles

1. Participant must be over age 18.
2. Limited to projects involving no more than minimal risk.
3. Total cash value of prizes (cash, gift certificates/cards, merchandise) awarded on any day cannot exceed $100.
4. There are no second chance drawings, meaning that individuals cannot be entered into a pool for a prize more than one time (i.e. participants 1-25 should be drawn on day 1, participants 26-50 on day 2, etc.).
5. The informed consent document must include a description of the lottery/raffle process including the date/location the drawing will take place, odds of winning and how winners will be notified.

Federally Funded Studies

1. Projects that receive federal funding may have additional requirements associated with participant compensation. Applicable regulations related to compensation must be followed.

FDA Regulated Studies

1. Projects under FDA regulations may not compensate participants in a sponsored trial with a coupon good for a discount on the purchase price of the product once it is approved for marketing.

REFERENCES

45 CFR 46.111(a)(3)
45 CFR 56.111(a)(3)
28 CFR 512.11(4,5)