Paying Subjects to Participate in Research

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Background:

It is common for subjects to be compensated for their participation in research, especially in the early phases of investigational drug, biologic or device development. Compensating subjects for participation in studies is not considered a benefit, but rather compensation for time and effort and lost wages. Compensation may include reimbursement for direct, out of pocket expenses (such as travel) or may be offered as an incentive when possible direct benefits to potential subjects are remote or non-existent. Compensation may be monetary or non-monetary.

The Institutional Review Board (IRB) must determine that the risks to subjects are reasonable in relation to anticipated benefits [21 CFR 56.111(a)(2)] and that the consent document contains an adequate description of the study procedures [21 CFR 50.25(a)(1)] as well as the risks [21 CFR 50.25(a)(2)] and benefits [21 CFR 50.25(a)(3)]. The Regulations (45 CFR 46.116 and 21 CFR 50.20) require that investigators seek consent only under circumstances that minimize the possibility of coercion or undue influence; and thus any compensation to study subjects will be evaluated based on the potential for coercion.

1. Q: What are the guidelines to follow when paying subjects to participate in research?

In accordance with DHHS regulations, the IRB has the following recommendations regarding proposed payments to study subjects:

1. Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study.
2. Payment to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn.
3. 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 to the IRB provided such incentive is not coercive.
4. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.

2. Q: Do subjects have to keep track of compensation payments for tax reasons?

Paying subjects for their participation in research may trigger tax consequences and privacy-related issues for the individual and reporting requirements for the University.

All income not otherwise excluded is gross income subject to taxation by the Internal Revenue Service (IRS). Compensation for subjects’ participation is income regardless of the form the
payment takes. Thus gift cards, gift certificates, or actual items (at their fair market value) would be taxable.

However, if total payment to an individual exceeds $75 for a particular study, or $600 (or more) in the calendar year, the amount must be reported to the University along with the participant’s Social Security Number. Subjects who receive more than $600 per calendar year will receive an IRS Form 1099.

All subject payment is handled through the University of Florida’s Human Subjects Payment (HSP) Program (M Turk payments are excluded). Subject information collected by HSP will include name, address, date of birth, and social security number in order for the University to comply with the IRS reporting requirements. This information is protected and access to the HSP Program site is restricted to certain staff with the assigned security role.

3. Q: What if subjects are only getting reimbursed for expenses incurred for study participation? Is that taxable too?

No, reimbursement for expenses incurred by the subject may be reimbursed without triggering tax consequences if the reimbursement is based on actual costs. The subject would need to present evidence of the expense such as receipts, bills, or canceled checks. Reimbursement for travel can include mileage to and from the research site at the IRS mileage rate applicable to the year in which the travel expenses were incurred.

4. Q: How is the IRB informed regarding compensation to subjects?

Information on compensation (including amount and schedule of planned compensation) must be included in the applicable section of the myIRB smartforms, consent document, and protocol (if applicable) and must be consistent across all documents.

If your study was initially approved without compensation, and now you have funding to offer compensation, a revision will need to be submitted and approved before subjects can receive compensation.

5. Q: Can advertisements mention that compensation is available for study participation?

Advertisements may state that subjects will be compensated, but must not emphasize the amount to be paid or display compensation as larger or bold font.

6. Q: What does the IRB look for when offering subject compensation?

Compensation cannot be coercive or unduly influence subjects. The IRB will review proposed subject compensation on a protocol-by-protocol basis including the type of compensation and amount, schedule, and pro-ration of payments to assure that the proposed compensation is not so significant that prospective subjects may consider participation in research that they may otherwise not participate in if it were not for the compensation.
If there is a bonus to be paid to subjects for completing the study, the IRB will determine if the amount to be paid is reasonable and not so large as to influence subjects to stay in a study when they may have otherwise withdrawn.

7. Q: Does the VA require anything different regarding subject compensation?

Yes, for research that involves the VA, investigators must complete the applicable myIRB VA Addendum smartform which includes information pertaining to subject compensation. In addition to IRB review of subject compensation, the NF/SGVHS Research and Development Committee (R&D Committee) will review all proposed payments for compliance with VA policies. For further information on compensation to subjects in VA Research, please see the VA Human Research Participant Protection Manual and/or VHA Handbook 1200.5 available through the VA Link: NF/SG VHS Research Website

8. Q: Are there restrictions when the study subjects could be foreign nationals?

Yes. Please see the Investigator Guideline on Research Involving Foreign Nationals.

9. Q: Are there any restrictions when the study involves UF Health Shands patients and visitors?

Yes. Per the Department of Health and Human Services Office of Inspector General (OIG), there are restrictions on compensating hospital patients and visitors, even when that compensation is for participation in a research study.

- Gift cards must fall within the OIG’s definition of nominal value, which is $15 or less per occurrence, and $75 or less in a calendar year (cannot be combined);
- Gift cards must not be considered a cash equivalent. Cash equivalent includes any gift cards that are redeemable for cash, or redeemable as cash to a nonspecific store/location (e.g. Visa, American Express, MasterCard gift cards);
- Gift cards must not be redeemable for health care items or services, which includes other general stores/locations (e.g. Target, Publix, CVS, Walgreens, Wal-Mart);
- Gift cards must follow the standard guidelines, be for a specific store or type of store/location, and are for appropriate things like Gas, Food, or Coffee (e.g. Circle K gas card, Einstein’s, Opus Coffee);
- Preferably, gift cards are funded through grants, contracts, or other funds authorized by the Office of Development or the Division of Sponsored Programs;
- All disbursements should follow UF or Hospital policies (depending on which are relevant) with regard to proper tracking and reconciliation;
- Gift cards should be appropriate in nature and provided without coercion or attempt to induce a patient or prospective patient from staying or returning for care or services.
Additional information regarding the use of gift cards is outlined in Shands Hospital core policy 04.019 “Provision of Free or Discounted Goods and Services, and Waivers of Copayments, Coinsurance or Deductibles to Patients.” Please contact UF Health Shands Compliance Services at 352-627-9050 with any questions.