



University of Puerto Rico Comprehensive Cancer Center (UPR-CCC) Research Subject Incentives/Compensation Management Policy

A. PURPOSE

As a responsible organization, the UPR-CCC recognizes the importance of encouraging individuals to participate in research as human subjects. Each subject contributes time and effort to research. Moreover, some subjects may also face potential risks including those that are physical, psychological, financial or reputational. This Policy is intended to establish guidelines for all payments and procedures for disbursement to human subjects participating in research at UPR-CCC.

Research Subject Incentives are those payments made to individuals to encourage their participation in research projects. Research Subject Compensation are those payments made to individuals to compensate them for their participation in research projects.

B. SCOPE

This Policy applies to incentives and compensation paid to human subjects in all research projects conducted at UPR-CCC, external study sites and/or clinical sites.

C. APPLICABILITY

Investigators, administrators, coordinators and other study team members are responsible for the management and tracking of the incentives and/or compensation. As programmatic and administrative leads for research projects, UPR-CCC Principal Investigators are accountable for the proper management and good use of incentives and/or compensation.

The Office of Sponsored Programs (OSP) is responsible for approving requests, disbursements and monitoring the good use of incentives.

D. DEFINITIONS

Incentives: reasonable cash payments or other types of incentives (gift cards, articles or goods) to be provided to subjects as a means of compensation for their time, effort and participation in research, or to encourage their participation in research. Incentives will have a value of \$50 or less under this Policy.

Compensation: is a payment to Research Subjects provided during/after engaging in the covered research activity. The researcher is compensating the subject for time and services related to a given study. Compensation may include cash payments; gift cards and certificates; articles or goods; travel and lodging reimbursement, and other items of value. Compensation has no set monetary limit under this Policy.

E. POLICY

The UPR-CCC permits reasonable cash payments or other types of incentives/compensation to be provided to subjects as a means of encouragement for participation or compensation for their contributions, as long as the following criteria are met:

- Incentives/Compensation are specifically approved in advance by the relevant Institutional Review Board (IRB).
- Monetary incentives and compensation should be based on the research subject's time allotted to and reasonable expenses incurred during the research study.

- Arrangements are made by the principal investigator, administrators and/or coordinators study teams to assure proper accounting of incentives/compensation made to subjects for fiscal accountability with due consideration for the privacy and confidentiality of the subjects.
- Unused incentives/compensation allocated for payments to subjects must be accounted for at regular intervals and returned to the Office of Sponsored Programs to ensure proper controls and accounting.
- Undistributed tangible articles or goods utilized as incentives/compensation, such as t-shirts, trinkets, remain the property of the UPR-CCC. This excludes articles or goods used for outreach purposes.
- Incentives/Compensation are requested and authorized through the Office of Sponsored Programs.
- UPR-CCC Projects must follow proper procedures and exercise internal controls when handling incentives/compensation.

F. PROCEDURES

I. Guidelines

1. The Principal Investigator will clearly define project personnel in charge of requesting, approving and keep custody of incentives and or compensation. Whenever possible, there will be a segregation of duties between those who request, approve, and become custodians and disbursers of incentive/compensation funds.
2. Each Project will have written procedures and documented controls that clearly outline the details of the processes for obtaining and disbursing human subject incentives/compensation.
3. Each Project will have a tracking, inventory, or logging process in place to ensure all funds, types and whereabouts of subject incentives/compensation are documented.
4. Using negotiable items, such as gift cards or gift certificates, requires very strict accountability. Gift cards/certificates are considered cash equivalents and negotiable items. Thus, they must be treated like cash, and researchers are accountable for their safekeeping and documentation of their distribution.
5. Each Project will maintain controlled access to resources such as cash/checks, cash equivalents (gift cards), deposit supplies, account information, and personal information.
6. Project personnel and/or members of the research team are not to pay subjects or purchase incentives/compensation using personal funds.
7. Incentives/compensation should not be withheld to ensure of a research subject's completion of the study. In most cases involving long term participation, researchers should give a reasonable prorated payment to avoid the appearance that the investigator is coercing the subject to continue in a study or is punishing the subject. The complete schedule of the payment plan should be clearly documented within the protocol and informed consent reviewed by the research subject.
8. Evidence and any unused subject incentives/compensation with no intended or specific future use should be returned within 7 days, unless approved by the Office of Sponsored Programs.
9. Verification and reconciliation of financial information should occur on a timely basis.
10. Research projects, including the use of human subject incentives/compensation, should be designed to minimize the risk of harm to subjects by collecting only necessary sensitive data and carefully managing its storage.

11. Appropriate evidence should be collected, maintained and provided to be consistent with UPR-CCC and Sponsor requirements.
12. When internal or external audits occur, Financial Operations will collect information from the Project to verify payment information.

II. Procedure for Managing Cash or Check Incentives/Compensation

1. Research Projects will prepare an estimated incentive/compensation disbursement schedule, according to their recruitment plan.
2. Designated Project Personnel will prepare cash or check requests on a weekly basis to match the number of subjects they will incentivize or compensate for the week. All requests must be authorized by the Principal Investigator.
3. Cash or check requests must be approved by the Sponsored Programs Accountant before being submitted to Financial Operations.
4. Designated Project Personnel will maintain receipts as evidence of disbursed funds. Receipts should be stored in a secured location to ensure subject confidentiality. Receipts will be requested during internal or external audit procedures or monitoring visits by sponsor.
5. As evidence of disbursed funds, the designated project personnel will maintain a log with the following information: subject identification number; date of disbursement; disbursement amount; name of disburser and signature of disburser.
6. The Principal Investigator will sign the log to certify the information contained in it.
7. The log will be filed along with financial documentation maintained by the Office of Sponsored Programs and Finance Operations.
8. Unused funds must be returned to Finance Department within 7 days.

III. Procedure for Managing Incentives/Compensation in the form of Gift Cards or Gift Certificates

1. Research Projects will prepare an estimated incentive/compensation disbursement schedule for each quarter, according to their recruitment plan.
2. Designated Project Personnel will prepare an **Authorization for the Purchase of Gift Cards as Incentives Form**, along with the purchase request on a quarterly basis. All requests must be authorized by the Principal Investigator.
3. Purchase requests must be approved by the Sponsored Programs Accountant before being submitted to Financial Operations.
4. Upon order receipt, designated project personnel must keep records of gift card numbers, and document the distribution and custody of gift cards.
5. Gift cards received will be kept by the Office of Sponsored Programs personnel and distributed to research project on a weekly basis.
6. As evidence of distributed gift cards/certificates, the designated project personnel will maintain a log with the following information: subject identification number; date of disbursement; disbursement amount; name of disburser and signature of disburser. Note that Sponsor may require the research subject to initialize or sign the log, please check with the Sponsored Programs Administrator.
7. The Principal Investigator will sign the log to certify the information contained in it.
8. The log will be filed along with financial documentation maintained by the Office of Sponsored Programs and Finance Operations.
9. Unused gift cards must be returned to the Office of Sponsored Programs within 7 days of distribution to the Project.

IV. Procedure for Managing Incentives in the Form of Tangible Articles or Goods

1. Research Projects will prepare an estimated incentive/compensation schedule, according to their recruitment plan. Articles or goods will be purchased according to this schedule.
2. Designated Project Personnel will prepare a purchase request for the articles or goods. All requests must be authorized by the Principal Investigator.
3. Purchase requests must be approved by the Sponsored Programs Accountant before being submitted to Financial Operations.
4. Upon order receipt, designated project personnel must keep records of articles or goods, and document the distribution and custody of articles.
5. As evidence of distributed articles or goods, the designated project personnel will maintain a log with the following information: subject identification number; type of article or good; date of distribution to subject; name of article custodian and signature of custodian. Note that Sponsor may require the research subject to initialize or sign the log. Please check with the Sponsored Programs Administrator.
6. The Principal Investigator will sign the log to certify the information contained in it.
7. The log will be filed along with financial documentation maintained by the Office of Sponsored Programs and Finance Operations.
8. Undistributed articles or goods must be accounted for during Project Closeout procedures.

This policy is recommended by the Research and Education Support Division Director on:



Research & Education Support
Division Director

Date: 2-26-2018

This policy is approved by the UPRCCC's Executive Director on:



Executive Director

Date: 2/26/2018