

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

A. PURPOSE

As a responsible organization, the CCCUPR 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 physical, psychological, financial, or reputational risks. This Policy is intended to establish guidelines for all payments and procedures for disbursement to human subjects participating in research at CCCUPR.

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

B. LEGAL BASIS

The CCCUPR Enabling Act, Act No. 230 of August 26, 2004, as amended, establishes the CCCUPR as the government entity principally responsible for the implementation of public policy regarding the prevention, orientation, research and provision of clinical services and treatment related to cancer. Pursuant to these objectives, Act 230-2004 authorizes the CCCUPR to develop and foster a research agenda focused on cancer and to establish its own administrative structure with its own operational regulations towards this end. Act 230-2004, Art. 5(b), (c), and (j). To that effect, the CCCUPR General Regulations authorize the Executive Director to adopt all policies, procedures, and regulations necessary to achieve the objectives of Act 230-2004, except the General, Human Resources, and Bid and Purchase Regulations, which shall be approved by the CCCUPR Board of Directors. General Regulations, Art. III, Sec. 3.

C. SCOPE

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

D. APPLICABILITY

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

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

E. DEFINITIONS

Incentives: reasonable cash payments or other types of incentives (gift cards, articles or goods) to be provided to subjects as compensation for their time, effort and participation in research, or to encourage their participation in research. Incentives will have a value of \$50.00 or less under this Policy.

Compensation: is a payment to Research Subjects provided during/after engaging in the covered research activity. The researcher compensates 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 valuable items. Compensation has no set monetary limit under this Policy.

Research Subject- an individual who is or becomes a research participant, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A research subject is also defined as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. Research subjects may include individuals from the community, CCCUPR employees, students, retirees, non-resident aliens, among others.

Drawing: For the purpose of this policy, drawing will be defined as an instance of selecting the Research Subject (s) winner (s) of an incentive for participating in a specific research study thru a truly random basis.

F. POLICY

I. Incentives/Compensation

The CCCUPR 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, if the following criteria are met:

- Incentives/Compensation are expressly 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 CCCUPR. This excludes articles or goods used for outreach purposes.
- Incentives/Compensation are requested and authorized through the Office of Sponsored Programs.
- CCCUPR Projects must follow proper procedures and exercise internal controls when handling incentives/compensation.

II. Lotteries, Raffles, and Drawings

Various federal guidelines, including IRS rules and other statutes, apply to lotteries. When proposing a research-related raffle or drawing as a form of compensation, researchers should keep these guidelines in mind to minimize the likelihood of triggering legal issues. The CCCUPR permits research-related drawing as a token of appreciation for research subjects' to be provided as a means of encouragement for participation or compensation for their contributions, if the following criteria are met:

- Researchers should use the term "drawing" or "raffle" rather than "lottery" since the latter terms imply the purchase of tickets by participants.
- The study is minimal risk
- Drawings are expressly approved in advance by the relevant Institutional Review Board (IRB).

- Eligibility for receipt of an incentive must not be contingent upon completing the research study. This means that the entire recruitment pool, not just those who enroll and/or complete the study, must be eligible for the incentives.
- Recipients must be selected on a truly random basis.
- 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.
- Cash cannot be distributed.

G. PROCEDURES

I. GUIDELINES

1. The Principal Investigator will clearly define project personnel in charge of requesting, approving, and keeping custody of incentives and 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 to ensure all funds, types, and subject incentives/compensation whereabouts are documented.
4. Using negotiable items, such as gift cards or gift certificates, requires 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 research team members are not to pay subjects or purchase incentives/compensation using personal funds.
7. Incentives/compensation should not be withheld to ensure 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 suspicion that the investigator is coercing the subject to continue in a study or punishing the subject. The complete schedule of the payment plan should be 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 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.

II. Procedure for Managing Cash or Check Incentives/Compensation

1. According to their recruitment plan, research Projects will prepare an estimated incentive/compensation disbursement schedule.
2. Designated Project Personnel will prepare cash or check requests every week to match the number of subjects they will incentivize or compensate for the week. The Principal Investigator must authorize all requests.
3. The Sponsored Programs Accountant must approve cash or check requests before submitting them 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 the 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; the name of disburser and signature of disburser.
6. The Principal Investigator will sign the log to certify its information.
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. According to their recruitment plan, research Projects will prepare an estimated incentive/compensation disbursement schedule for each quarter.
2. Designated Project Personnel will prepare an Authorization for the Purchase of Gift Cards as incentives Form and the purchase request every quarter. The Principal Investigator must authorize all requests.
3. The Sponsored Programs Accountant must approve purchase requests 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 the research project weekly.
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, the name of disburser, and signature of disburser. Note that the 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 its information.
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 seven days of the 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. The Principal Investigator must authorize all requests.
3. The Sponsored Programs Accountant must approve purchase requests 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 the subject; the name of article custodian and signature of custodian. Note that the 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 its information.
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.

V. Procedure for Drawings

- The Principal Investigator must develop a protocol for the drawing. To further avoid the possibility that a drawing would be perceived as a lottery, the protocol should describe procedures for ensuring that all individuals who participate in the research will be allowed to enter the drawing. This would encompass individuals who are invited to participate but decline prospective ineligible subjects, and the researchers withdraw subjects who enroll but later withdraw/. Additionally, the protocol should affirm that the drawing may be entered by any individual who asks to be included.
- The protocol and consent document(s) should also include the following information:
 1. Description of the prizes, including estimated value and the total number of prizes to be awarded.
 2. Justification for not incentive/compensate all Research Subjects.

3. The odds of winning a prize, if known, or descriptive language similar to this:

“For any drawing, the odds of winning a prize depend on how many people are entered in the drawing. As we do not know how many people will participate in this study-related drawing, we cannot predict what will be the odds of winning a prize.”

4. The approximate timing of the drawing (e.g., month/year).
5. How prize winners will be notified.

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

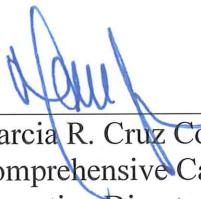
Elba J. Caraballo

Elba V. Caraballo Rivera PhD, MS
Division of Research & Education Support
Director

05/19/2022

Date

This policy is approved by the Institution’s Executive Director on:



Marcia R. Cruz Correa, MD PhD
Comprehensive Cancer Center
Executive Director

05/20/22

Date