



ADMINISTRATIVE POLICY MANUAL

Subject: Research Studies – Payments to Participants

Effective Date: 7/01/12
Approved by: Vice President of Finance/CFO
Vice President/Chief Compliance Officer
Responsible Parties: Senior Executive Director of Finance
Executive Director of Richard A. Henson Cancer Institute
Revised Date: 4/16
Reviewed Date: *
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Policy:

Certain research study sponsor agreements may necessitate payments to the research subject. Sponsors may directly compensate participants for their time, effort and expenses related to their participation. Compensation can be in the form of money, certificates, products, or other incentives and are subject to Internal Revenue Service tax laws and it is the responsibility of the study sponsor to ensure all rules and regulations are met.

Some payments to participants may come through PRMC to the participant in accordance with the study agreement; this policy details that process.

Uniform methods for documenting, tracking, and providing approval are needed in three key areas: identifying IRB approved human subject compensation, tracking individual subject payments, and reconciling participant payment accounts. Failure to adequately manage these operations jeopardizes the financial and ethical integrity of human subject research at PRMC. The IRB of record for a study is required to approve, in advance, the method and amount of compensation to any human research participant. Investigators may not deviate from the amount, type or timing of the payment without first obtaining a modification to their approved human subjects consent.

PRMC will issue required tax reporting to the IRS and participant when paid by PRMC; when paid directly by the sponsor, the sponsor will have tax reporting responsibility. Questions about this policy shall be directed to the Senior Executive Director of Finance or designee.

Payment Administration in Research: A given research study may have one or more research participant payment funds. The level of compensation must be reasonable and appropriate based on the activity and cannot be perceived as unduly influencing study participation due to the level of remuneration.

Procedure:

Research Participant Payments Schedule: If research payments are to be made, the Principal Investigator must complete a Subject Payments Schedule (Appendix A). This request is the basis for establishing all participant payment accounts and authorizing all participant payments. It documents the IRB authorized participant payment events, the types of payment and payment amounts.

Methods of Payment to Participants: All fund transactions must be recorded in the Subject Payment Form (Appendix B) and include:

- Protocol Name or Number
 - Principal Investigator
 - Department
 - Visit or Payment Event
 - Payment Type
 - Dollar Amount or List of Non-Monetary Items
 - Name or Subject ID
 - Payee Signature
1. PRMC Check – Payment by institutional check is the preferred method of participant payment; however, this may be used only when participants are not anonymous.
 - Prepare a Payment Request form AP102A payable to the participant. Form available under forms on the iPortal.
 - Prepare a privacy waiver that states the following and includes the participant's printed name, signature and date:
"I understand that I will no longer be an anonymous participant in this study. I also understand that my personal information, including my name, address, and Social Security number, will be released only to the Accounting Office of PRMC for the purpose of payment to me and for tax reporting, if required."
 - Participant's SSN is required in order to complete necessary tax reporting.
 - On the AP Payment Request Form indicate if the study sponsor needs to be billed for the amount paid to participant. If billing is required, the Finance Department will create the invoice/bill and provide it to the research study nurse for submission to the sponsor.
 - Send the approved Check Request, copy of IRB approval letter, and copy of the signed privacy waiver to the Disbursements Office.
 2. If subject is anonymous – contact the Senior Executive Director of Finance for payment arrangements.
 3. Non-Monetary Items –
 - IRB approved items such as books, coolers, calendars, etc., are either provided by the sponsor or acquired by the research department. Regardless of the method by which the research department obtains non-monetary items for use as incentive payments to research participants, these items are considered payments and must be tracked. Likewise, reasonable measures must be in place to safeguard and secure the non-monetary items.
 - No collection of the participant's SSN is required unless it is anticipated that the participant will receive incentive payments, from all sources, totaling \$600.00 (subject to change by IRS regulation) or more during the calendar year.
 - Complete Subject Payment Form and maintain in the master research records.

4. Reimbursement of Expenses to Participants -

- Travel expenses – Prepare travel voucher and retain receipts for hotel, meals, transportation, etc., in the research records. In order to protect anonymity of the subject, no receipts should be sent to Accounting.
- Complete Subject Payment Form and submit to study sponsor.

Approved by:

Bruce Ritchie
Vice President of Finance/CFO

Tim Feist
Vice President/Chief Compliance Officer

Appendix A

SUBJECT PAYMENTS SCHEDULE					
Short Study Title: _____					
Principal Investigator: _____					
IRB Number: _____					
Lead Research Coordinator: _____					
Department: _____					
Date Study Opened: _____					
Contracted Subject Enrollment: _____					
Visit or Payment Event (Include Payment Details)	Indicate Monetary Value of One Payment			Max. Dollar Value	Max # of Gift Items
	Cash	Check	Gift Card		
Total Dollar Value Possible for 1 Research Participant				\$	
Total Dollar Value Possible for Max # of Research Participants				\$	
Count of Gift Items for 1 Research Participant					
Count of Gift Items for Max # of Research Participants					
<p>Principal Investigator: _____ Date: _____</p> <p><i>As PI, I am certifying that the subject payment information listed on this schedule have been IRB approved</i></p> <p>Research Nurse: _____ Date: _____</p> <p>Finance Dept. Rep: _____ Date: _____</p>					

SUBJECT PAYMENT FORM

Short Study Title: _____

IRB/ Number: _____

Principal Investigator: _____

Department: _____

Visit or Payment Event: _____

Payment Type: Cash Check Money Order Gift Card Non-monetary Item

Dollar Amount or List and Count of Non-Monetary Items: _____

Serial Number on Gift Card: _____

Payee Signature: _____
(Research Participant)

Date: _____

Payee Printed Name: _____

Signature: _____
(Research Nurse or Designee)

Date: _____

Printed Name: _____

PRMC Witness Signature: _____

Date: _____

PRMC Witness Printed Name: _____