



## Human Research Protection Program Policy

### **PAYMENT TO PARTICIPANTS IN HUMAN SUBJECTS RESEARCH**

#### **POLICY**

Participants in human subject research (HSR) may be paid for their participation as long as the payment is fair and reasonable. The University of Cincinnati (UC) Institutional Review Board (IRB) must review and approve all payment amounts and methods to assure they minimize the possibility of coercion or undue influence to participate in the study.

#### **CRITERIA FOR IRB APPROVAL**

The following criteria must be met before the IRB may approve a study's payment amounts and methods, unless the IRB finds that an exception will not result in coercion or undue influence to participate in the study. When considering these criteria the IRB must take into consideration the potential participants' medical, financial, emotional, employment and educational status, available community and institutional resources, and any other circumstances impacting the determination of fair and reasonable payment. The amount, method and schedule of payment must be explained in the informed consent document (ICD).

1. The amount of payment must be comparable to other HSR involving similar time, effort and inconvenience of participants.
2. Participants may be reimbursed for out-of-pocket expenses such as parking or travel costs.
3. The method of payment must be appropriate in relation to the degree of participant privacy and confidentiality required by the study.
4. The timing of disbursement must minimize the possibility of coercion or undue influence to participate. In general, payment should be made at the beginning of participation, or pro-rated amounts should accrue as the study progresses. If participation requires an extended length of time or multiple study visits, payment should not be dependent upon the participant completing the entire study.
5. Any amount paid as a bonus for completing the entire study must be reasonable and must not be likely to coerce or unduly influence a participant to remain in the study even though they would otherwise have withdrawn.

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6. No payment may be made in exchange for referrals of potential participants ("finder's fees").
7. No payment may be made to the research staff, Principal Investigator (PI) or the PI's department or other organization that is tied to the rate or timing of enrollment, designed to accelerate recruitment ("bonus payments").
8. Raffles, lotteries, and drawings are generally not a preferred method for paying participants; however, the IRB will on a case-by-case basis determine whether raffles, lotteries, and drawings may be used to recruit or retain participants in certain minimal risk studies.
9. Compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing is not allowed.
10. Veterans Administration Medical Center (VAMC) policy prohibits paying a patient to participate in VAMC research when the research is integrated with the patient's medical care and when it makes no special demands on the patient beyond those of usual medical care. VAMC research is defined as research using VAMC facilities, employees, resources or patients.
11. Payment may be permitted in VAMC research in the following circumstances.
  - a. **No Direct Participant Benefit**  
When the study to be performed is not directly intended to enhance the diagnosis or treatment of the medical condition for which the volunteer is being treated, and when the standard of practice in affiliated non-VAMC institutions is to pay participants in this situation.
  - b. **Others Being Paid**  
In multi-institutional studies, when human subjects at a collaborating non- CVAMC institution are to be paid for the same participation in the same study at the same rate proposed.
  - c. **Comparable Situations**



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In other comparable situations in which, in the opinion of the IRB, payment of participants is appropriate.

- d. **Transportation Expenses**  
 When transportation expenses are incurred by the participant that would not be incurred in the normal course of receiving treatment and which are not reimbursed by any other mechanism.

### ACCEPTABLE FORMS OF PAYMENT

Forms of payment to participants may include, but are not limited to, gift certificates, gift cards, debit cards (e.g., greenphire ClinCard), cash and merchandise. Documentation of payment to individual participants may be required for audit purposes, but should be retained with confidentiality protections similar to the study's research data.

#### Applicable Regulations and Documents:

- 21 CFR 50.20
- 45 CFR 46.116
- HRPP Procedure 106 *Participant Outreach*
- VA Handbook 1200.05

<b>Adoption Date:</b>	<b>Created by:</b>	<b>Date of Revision:</b>	<b>Revised by:</b>	<b>Summary of Revision:</b>
11/2005	M. Belskis	07/2007	J. Lindwall	Removal of procedures for payments to participants to be documented in the protocol.
		9-13-12	C. Norman	Revise wording for clarity and to remove redundant language. Add HRP Procedure 106, HRP Procedure 203 and VA Handbook to Applicable Documents.
		9/2014	A.Braggs-Brown	Revised to reflect AAHRPP recommendations
		2/2015	M. Linke	Revised to include exceptions to the use of raffles, lotteries, and other games of chance as recruitment incentives

Date Adopted <u>February 2015</u> Signature <u>signed copy on file</u>
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