


Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
	SUBJECT PAYMENT		
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PURPOSE: The purpose of this SOP is to describe the procedures that PIs and designated research personnel will follow at the CRC to ensure compliance with all federal and local regulations and guidelines to assure subjects are protected from coercion to participate in a study.

SCOPE: This SOP applies to all human subject research conducted at the CRC that fall under the purview of the USF Institutional Review Board (IRB) or USF- relied upon IRBs.

RESPONSIBILITIES: The investigator is responsible for ensuring that any payment or remuneration offered to human subjects research participants is fair and not an undue inducement to participate.

DEFINITIONS:


Coercion: Occurs when an overt threat of harm is intentionally presented by one person in order to obtain compliance.

Human Subject: An individual about whom an investigator conducting research obtains data through intervention or interaction or private, identifiable information. This includes individuals who are participants in research and exposed to test articles or controls as well as normal healthy subjects enrolled in a research study.

Payment: Cash or other value provided to human research subjects, provided as compensation for time, inconvenience, and/or effort associated with research participation. Also referred to as remuneration


Remuneration: Payment for participation in research.

Undue Influence: Occurs through an offer of excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance. Compensation that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable

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PROCEDURE:

1. The PI may provide various alternative methods of payments to research study subjects via the following options:
 - 1.1. University check through Accounts Payable
 - 1.2. Gift cards purchased via University Purchasing Card or after receiving a Faculty Research Advance via Accounts Payable
 - 1.3. Cash acquired after receiving a Faculty Research Advance via Accounts Payable
 - 1.4. ClinCard
2. The PI and designated research personnel will comply with the respective method of payment procedures described to in Appendix DD
3. For PIs and study teams who opt to use the ClinCard method of payment, please refer to Appendix EE: *ClinCard Admin Portal Quick Reference Guide*
4. The PI and study coordinator/ regulatory coordinator will inform the USF IRB or relied-upon IRBs of compensation to research participants in the IRB application for initial review.
5. He/ she will provide detailed information regarding remuneration to subjects in the appropriate field of the IRB application for each submitted protocol.
6. The PI and research designee will report the following information to the IRB.
 - 6.1. Amount of remuneration
 - 6.2. Method and form of remuneration
 - 6.3. How payments will be prorated should the individual withdraw from the study prior to completion of all study related activities
 - 6.4. Payment schedule of disbursement
 - 6.5. Any changes to the amount of compensation or method at the time of continuing review
 - 6.6. Any changes to compensation, the amount, method or timing, via an amendment to the approved study. These changes must be reviewed and approved prior to the initiation of such changes.

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PROCEDURE (cont.):

7. The PI/ research designee will ensure prompt payment to research subjects as outlined in the payment schedule disbursement in the informed consent document.
8. Designated research personnel will maintain all records and safeguard gift cards same as cash. PIs/coordinators are responsible to maintain logs on each compensated participant: gift card ID, value, subject name, W9 document with regular reconciliation
9. The PI and research personnel should be familiar that the IRB offers the following guidance regarding the appropriate amount, method and timing of compensation awarded to individuals for their participation in research:
 - 9.1. Compensation must be reasonable and equitable in the selection of participants;
 - 9.2. Compensation must not be coercive or present an undue influence to participation
 - 9.3. Compensation must be based on a fair assessment of the complexity of the study, the type and number of procedures which will be performed, the time involved in the participation of the study, and inconvenience of subjects;
 - 9.4. Compensation must accrue as the study progresses (i.e., be prorated) and cannot be contingent upon completion of all study related procedures or visits. Prorated payments should be made regardless of the subject's withdraw from the study being voluntary or involuntary;
 - 9.5. Compensation which includes a bonus for completion of all study related procedures or visits must be reasonable and not so large that it would unduly influence individuals to continue participation when they would have otherwise withdrawn;
 - 9.6. Compensation must be fully outlined in the informed consent document including prorated payments and total compensation as well as the method and timing of compensation;
 - 9.7. Any changes to compensation, the amount, method or timing, must be submitted to the USF IRB or External IRBs for review and approval;
 - 9.8. Compensation to minors for participation in the study will receive additional ethical scrutiny by the IRBs due to the vulnerability of this population. Compensation to this group of subjects may present additional concerns regarding undue influence by financial reward. Additionally, payment to parents for a child's participation in research will receive this additional ethical scrutiny;

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- 9.9. Sponsor coupons for a discount on the purchase price of the product once it has been approved for marketing is prohibited as compensation for participation;

PROCEDURE (cont.):

- 9.10. Compensation shall not be listed as a benefit to participation in research and should not be outlined as such in the informed consent document or considered by the IRB in the assessment of the risks and benefits to subjects;
- 9.11. For research involving veterans, please refer to details outlined in USF HRPP Policy and Procedures Manual -Compensation to Human Research Study Subjects.
- 9.12. In the State of Florida, it is unlawful for any health care provider to offer, pay, solicit, or receive remuneration for the referral of a patient (Florida Statute 456.054); therefore, the IRB does not allow payments designed to accelerate recruitment (also known as bonus payments) or allow referrals that result in a “finder’s fee” payment.

REFERENCES:	21 CFR 50.20 General Requirements of Informed Consent 21 CFR 312.60 General Responsibilities of Investigators 45 CFR 46.116 FDA Information Sheet, Guidance for Institutional Review Boards and Clinical Investigators, Payment to Subjects, 1998 May 1997 International Conference on Harmonization (ICH) Good Clinical Practices The Belmont Report, 1979 Nuremburg Code, 1947
RELATED POLICIES:	USF HRPP Policy and Procedures Manual-Compensation to Human Research Subjects SOP #402: Informed Consent Process
APPENDICES:	Appendix DD: Accounting for Payments to Research Study Subjects Appendix EE: ClinCard Admin Portal Quick Reference Guide
REVISION HISTORY: Keep a running history of all revision dates.	

Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	06/15/2016

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