**PURPOSE:** The purpose of this SOP is to describe the procedures that PIs and designated research personnel will follow at Kent State 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 KSU that fall under the purview of the KSU Institutional Review Board (IRB) or KSU- 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.

**PROCEDURE:**

1. The PI may provide various alternative methods of payments to research study subjects via the following options:
   1. University check through Accounts Payable via check request.
   2. Gift cards or Certificates
   3. Cash

Refer to the Procedures of Compensating Research Subjects policy for more detailed information.

1. The PI and designated research personnel will comply with the respective method of payment procedures described to in the Procedures for Compensating Research Subjects.

1. The PI and study coordinator/ regulatory coordinator will inform the KSU IRB or relied-upon IRBs of compensation to research participants in the IRB application for initial review.
2. The PI and research designee will report the following information to the IRB.
   1. Amount of compensation.
   2. Method and form of compensation.
   3. How payments will be prorated should the individual withdraw from the study prior to completion of all study related activities.
   4. Payment schedule of disbursement.
   5. Any changes to the amount of compensation or method at the time of continuing review.
   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.

1. The PI/ research designee will ensure prompt payment to research subjects as outlined in the payment schedule disbursement in the informed consent document.
2. 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 (if applicable) with regular reconciliation.
3. The PI and research personnel should be familiar with the following IRB guidance regarding the appropriate amount, method and timing of compensation awarded to individuals for their participation in research:
   1. Compensation must be reasonable and equitable in the selection of participants;
   2. Compensation must not be coercive or present an undue influence to participation
   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;
   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;
   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;
   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;
   7. Any changes to compensation, the amount, method or timing, must be submitted to the KSU IRB or external reviewing IRBs for review and approval;
   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;
   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;
   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;

|  |  |
| --- | --- |
| **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:** | IRB Policy - Compensation to Human Research Subjects  SOP #402: Informed Consent |
| **APPENDICES:** | Procedures for Compensating Research Subjects |
| **REVISION HISTORY:** Keep a running history of all revision dates. | |

* 1. In the State of Ohio, it is unlawful for any health care provider to offer, pay, solicit, or receive remuneration for the referral of a patient; 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. NEED COMMENT FROM UNIVERSITY COUNSEL ON THIS

|  |  |  |
| --- | --- | --- |
| **Approval Date** | **Effective Date** | **Review/Revision Date** |
|  | **01/29/2017** |  |
|  |  |  |
|  |  |  |