SOP: Payments to Research Participants				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
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1 PURPOSE

1.1 This procedure establishes the process to offer payment to research participants.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 All research payments must be fair, reasonable, and minimize the possibility of undue influence.

3.2 Research payment is not considered a benefit to participation. Payment must be itemized according to the following categories: reimbursement, compensation, and/or incentive.

4 DEFINITIONS

4.1 In this procedure “undue influence” means an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance that could lead a participant or potential participant to make a decision against their own best interest.

4.2 In this procedure “reimbursement” means payment for reasonable out of pocket research-related expenses incurred by research participants. Examples may include, but are not limited to: bus fare, mileage for reimbursement, parking fees, and/or child care.

4.3 In this procedure “compensation” means payment to compensate research participants for their time, effort, and/or burdens imposed by the research.

4.4 In this procedure “incentive” means payment to improve recruitment and participation or completion rates.

5 RESPONSIBILITIES

5.1 The principal investigator (PI) is responsible to ensure these procedures are carried out.

6 PROCEDURE

6.1 Payment purpose

- 6.1.1 The three primary categories for research payment are: reimbursement, compensation, and incentive.
- 6.1.2 Researchers must clearly describe all payments with respect to the categories within the designated section(s) of the research protocol and consent form(s).

6.2 Payment amount

- 6.2.1 Payment amount must not be so excessive as to increase the possibility of undue influence. Payment may be considered undue if it distorts an individual’s decision to participate in or continue with the research.
  - 6.2.1.1 Examples of such influence include payments that cause prospective participants to unreasonably discount or fail to consider research risks and/or act in a way that is inconsistent with their personal values or beliefs.
- 6.2.2 Non-monetary payment (e.g., course extra credit) must not be so great as to diminish the voluntariness of consent or compromise a participant’s examination and evaluation of risks associated with participation.
  - 6.2.2.1 If extra credit is offered to student participants, they must be provided with and informed of non-research alternatives involving comparable time and effort to obtain the extra credit.

6.2.3 Researchers must clearly describe and justify all payment amounts within the designated section(s) of the research protocol and clearly describe within the consent form(s).

6.3 Payment schedule

6.3.1 Payment must not be contingent upon completion of study procedures. For research involving significant duration or multiple interactions or interventions, payment must be prorated according to the proportion of study participation a participant has completed.

6.3.2 Researchers must include a payment disbursement schedule within the designated section(s) of the research protocol and consent form(s).

6.4 Payment method

6.4.1 Payment must not include a coupon good for a discount on the purchase price once a product has been approved for marketing.

6.4.2 For drawings, prohibited terms include, but are not limited to: “raffle”, “lucky”, “sweepstakes”, or “winning.” Acceptable terms for this method include, but are not limited to: “drawing” and participants being “selected.” All terminology associated with drawings is subject to the discretion of the HRPP/IRB.

6.4.3 Researchers must clearly describe the method of payment, including all odds of being selected for drawings, within the designated section(s) of the research protocol and consent form(s).

6.4.4 For research that is subject to the Virginia Tech Controller’s Office Procedure 23715c: Selecting and Paying Human Subject Participants, please refer to this procedure for specific guidance regarding method of payment.

6.5 Payment terms

6.5.1 Researchers must specify the conditions under which a participant would receive partial or no payment (e.g., what will happen if the participant withdraws prior to completing the research or the investigator removes a subject from the study for certain reasons).

6.5.2 Researchers must clearly describe the terms of payment within the designated section(s) of the research protocol and consent form(s).

6.6 Research advertisements

6.6.1 Research payments must not be emphasized in any fashion within research advertisements (e.g., large/bold font, exclamation points, etc.). See “Worksheet: Advertisements (HRP- 315.1).

7 MATERIALS

7.1 WORKSHEET: Advertisements (HRP-315.1)

8 REFERENCES

8.1 21 CFR §50.20

8.2 45 CFR §46.116

8.3 U.S. Food & Drug Administration. Information Sheet. Payment and reimbursement to research subjects: Guidance for institutional review boards and clinical investigators, January 2018.

8.4 Office for Human Research Protections. Informed Consent FAQs.

8.5 Secretary Advisory Committee on Human Research Protections. Attachment A- Addressing Ethical Concerns Regarding Offers of Payment to Research Participants, July 2019.

8.6 Virginia Tech Controller’s Office Procedure 23715c: Selecting and Paying Human Subject Participants

8.7 U.S. Food & Drug Administration. Information Sheet. Institutional Review Boards Frequently Asked Questions: Guidance for institutional review boards and clinical investigators, January 1998.