I. PURPOSE

Participant payment arrangements may affect the equitable selection of participants and may also unduly influence subject decision-making during the informed consent process. The purpose of this standard operating procedure is to define the types of payments made to subjects, and to provide guidance as to acceptable practices.

II. POLICY STATEMENT

The IRB is responsible for review and approval of participant payment arrangements offered to a subject or family, as part of a research protocol. The IRB will permit reimbursement to families for expenses related to travel, time or inconvenience and will permit compensation for study participation when the compensation is considered fair, honest and appropriate. For studies that involve greater than minimal risk, the IRB will apply a "wage" model for determining fair and appropriate compensation.

III. SCOPE

These policies and procedures apply to all protocols submitted for IRB review.

IV. DEFINITIONS

Compensation or Incentive Payments: A predetermined payment of cash or cash equivalent provided to research subjects for the time, effort, inconvenience, and general expense of participating in a research activity. Payment may be made on a one-time basis or several payments may be made over a period of time. Compensation is considered taxable income.

Reimbursement: A payment to research subjects/families for direct, out-of-pocket research-related expenses based on actual expenses (e.g., transportation, parking, lodging, meals, childcare, etc.) incurred as a result of their participation in research. The actual expenses must be based upon (1) receipts (or other valid, acceptable documentation) that are collected and submitted for the exact amount as the original expense, or (2) allowances for lodging or meals and incidental expenses up to the IRS-set per diem rates. Reimbursement for actual expenses is not considered taxable income.

Note: Payments for expenses that are not based on receipts, actual costs incurred or IRS-set per diem rates are considered compensation by the IRS and are therefore taxable income.

Tokens of Appreciation: Tokens of appreciation are small gifts of appreciation that include tangible items of nominal value such as T-shirts, mugs, calendars, books, stuffed animal, tote bag, etc. In order to ensure compliance with tax reporting requirements, a maximum value of $100 has been set for Tokens of Appreciation. Tokens of Appreciation are neither compensation/incentive nor reimbursement and are not considered taxable income.

Wage Model: A method of determining the amount of payment by using a standardized hourly wage and an estimated time for completing the research task.

V. PROCEDURES

A. Permissible Forms of Payment

1. Payment to compensate for time, effort and inconvenience of research participation is permissible, provided that it does not represent an undue inducement.

2. Payment for adults should be based on a wage model, calibrated to the least well off amongst anticipated study participants.

3. Payment to children 9 years and older should be based on a wage model, with the wage scaled to those that children can actually earn for common jobs such as baby-sitting or shovelling snow.

4. Payments for children younger than 9 years should either be non-monetary or tokens of appreciation.

B. Non-Permissible Forms of Payment or Compensation

The IRB does not permit any of the following forms of payment/compensation or financial arrangements unless the IRB grants a waiver (e.g. when the impact of payments on subject recruitment or retention is the object of the study):

1. Lottery or prize drawings for individuals who participate in research.

2. Use of finders' fees, recruitment bonuses or incentives, other than referral payments to participants as outlined in the Office of Research Compliance and Regulatory Affairs policy 'Bonus Payments in Clinical Research'.

3. A coupon good for a discount on the purchase price of the product once it has been approved for marketing.

4. Waiver or subsidization of copayment or coinsurance amounts, or payment for standard of care services following insurance denial by a sponsor.

C. Investigator Responsibilities

1. The investigator must include information describing when and how the proposed payments will be made to a participant in either the protocol or in the IRB application. The informed consent document, must fully disclose to whom payments are due, the type of payment (reimbursement or compensation or token of appreciation) and the amount of each type of payment.

2. A change in the amount or terms of compensation during the course of the research is considered a protocol modification, and must be submitted to the IRB

for review and approval.

D. IRB Review

1. When reviewing the protocol and IRB application, the IRB will ensure that the following conditions are met:

(a) The protocol or IRB application should disclose the amount, form of payment, timing and purpose of the payment. The IRB will review the documentation and determine if the amount of payment is appropriate for the procedures, time, effort and inconvenience involved.

(b) Either the IRB application or the protocol must state who will receive the payment.

(c) The payments are insufficient to unduly induce subjects to participate and thereby assume risks that they would not otherwise agree to.

2. When reviewing the consent form, the IRB will ensure that the following conditions are met:

(a) The consent form does not include payment as a benefit;

(b) The purpose, timing, form and amount of payments have been specified;

(c) Payments to subjects as specified above, are listed separately from payments to parents/guardians;

(d) When payment or reimbursement will be made with bankcards, the consent form will include information that the bank will have access to identifiable information but not to any medical information;

(e) Payment to subjects and families are not conditioned upon completion of the research; if a subject withdraws from a study, they must be offered payment for the portion of the study completed.

- For studies lasting only a few days, a single payment date at the end of the study, even to participants who had withdrawn before that date, is acceptable.
- It is permitted to withhold payment until the time specified in the consent form.

(f) When reviewing the provision of smart devices (e.g.,an iPad, "smart phone", "smart watch" or "Fitbit") to study participants as form of payment, the IRB will:

- Consider the market value of such devices and ensure it does not

represent an undue inducement.

- Ensure that the provision will not induce potential subjects to choose a particular provider/supplier (e.g. subjects are already CHOP patients), or be tied to use of a reimbursable product.
- Not permit advertising "free" devices.

3. When payment to an individual could exceed $600 in a calendar year, the study team must disclose to subjects that CHOP will be required to issue IRS Form 1099 to the parent and child.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111(a)(3), 45 CFR 46.116	21 CFR 50.20, 21 CFR 56.111(a)(3)

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 105: IRB Review Processes	SOP 703: Review of Recruitment Materials
SOP 301: Human Subjects Research Submission Requirements	SOP 402: Criteria for Initial IRB Approval
SOP 701: Required Elements of Consent and Documentation of Consent	CHOP Office of Research Compliance and Regulatory Affairs: Bonus Payments in Clinical Research Policy

VIII. RESPONSIBILITIES

Title	Responsibility
IRB Reviewer	Responsible for reviewing compensation plan for adherence to IRB policy on wording in recruitment materials and amount of payment.
Chair, CPHS and Director, Human Subjects Research	Responsible for establishing and periodically reviewing and modifying (as appropriate) the IRB policy on payment to subjects.
Principal Investigator	Responsible for submitting a payment plan to the IRB for

	approval prior to implementation.

IX. ATTACHMENTS

X. REVISIONS:

5-27-09:	Revision includes minor editorial corrections, update of title for Director, Human Subjects Research; additional references to SOPs 301, 402 and 703; removal of Section V. Principles to harmonize with current SOP template; addition of the definition of wage-model; addition of breakdown of payment by age of subject; and reorganization to include a section on Permissible Forms of Payment.
6-9-10:	Revision includes minor editorial changes due to the transfer to from paper to electronic (eIRB) submissions and to V.D.3 to agree with revised SOP 703 regarding increased flexibility for the IRB to determine whether a stated payment amount on a given recruitment material is appropriate.
7-8-10:	Revised to reflect AAHRPP's recommendations.
8-1-14:	Updated to reflect CHOP policy on Payment to Human Subjects.
7-28-16:	Updated for consistency with ORCRA policy 'Bonus Payments in clinical Research'.
9-25-18	Revised to update definitions and SOPs and minor edits.
12-22-22	Revised to update current processes and recent legal guidance.

XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 12/22/22
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS