Participant and Caregiver Remuneration	CR-306
Clinical Research Standard Practices	**Effective Date:** September 2024

SCOPE AND PURPOSE This document is applicable to the following roles within Penn State College of Medicine and Penn State Health entities engaged in clinical research:

X	Principal Investigator	X	Regulatory Specialists
X	Sub-Investigators		Key Study Ancillary Personnel
X	Study Coordinators/Associates	X	Financial Analyst/Contract Management Accountants
	Data Specialist	X	Central Research Office Personnel

This policy describes how research participants and their caregivers may be remunerated for clinical research conducted at Penn State College of Medicine and Penn State Health (collectively "Institution") in accordance with Penn State University's overarching policies. Research participation can inconvenience a research participant and their caregiver in multiple ways. It is not necessary, required, or desirable that all subjects involved in clinical research receive monetary and/or non-monetary remuneration for their participation in clinical research. Nonetheless, an investigator, study team, and/or sponsor may wish to provide remuneration. Therefore, the remuneration for participation must be appropriate to the specific demands of the study. Various forms of remunerations may be classified as reportable or non-reportable income with the United States Internal Revenue Service (IRS) policies and guidelines. This policy will define how such remuneration will be classified to remain in compliance with IRS standards.

For the purposes of this policy, the term "recipient" shall be defined as the participant or caregiver who will be the recipient of the payment (whether stipend, travel, or other reimbursement).

This policy may be shared with Sponsors and/or CROs upon request.

POLICY AND PROCEDURE STATEMENTS

1. General
    a. Definition
        i. Stipend – compensation to ease the non-monetary, intangible burdens and inconveniences that patients and their caregivers may face once enrolled in a clinical research study.
        ii. Travel – reimbursement for the associated cost incurred by participants and/or their caregivers, to attend research visits such as mileage, parking, taxi/rideshare fares, tolls, and train/airfare.
    b. The Institution provides applicable remuneration to the recipient through Penn State's Greenphire account unless Sponsor's payment vendor is used.
    c. When the Institution disperses remuneration, Institutional Overhead is applied to all payments to recipients to cover the applicable cost of Greenphire.
    d. The grant, contract, or subaward is the agreement between the Institution and the Sponsor/funding agency as to what remuneration the recipient will receive. The

informed consent form (ICF) is the agreement between the Institution and the recipient as to what remuneration the participant will receive. The ICF must be congruent with the grant, contract, or subaward.

e. Responsibilities related to remuneration
    i. The Clinical Trials Office will negotiate remuneration based on the requested amounts by the investigator and study team for externally funded studies budgeted by the CTO.
        - Changes to remuneration amounts will be communicated with the investigator and study team throughout the negotiation. The final remuneration amount will be provided in Contract Notes and will be entered into the Clinical Research Management System if the Institution is dispersing the remuneration.
    ii. The PI and study team will inform the CTO or departmental staff, depending on who is developing the budget, of remuneration amounts for grants and internally funded studies.
    iii. The PI or study team is responsible for ensuring the ICF is congruent with the grant, contract, or subaward.
        - Refer to the CTO Infonet site should a recipient be provided with remuneration amounts that differs from what is listed in the ICF or is given the amount of remuneration listed in the ICF, but the ICF differs from what is listed grant, contract, or subaward.
        - When appropriate the ICF should define what remuneration is for the participant and what is for a caregiver. In certain situations, the caregiver may also be considered a participant as well though not receiving research treatment.

f. Declination of Payments
    i. A recipient may choose to decline to receive payment for stipend or travel reimbursement. In alignment with Belmont Report principle of Respect for Persons, a participant or caregiver may choose to not accept the offer payments. In deciding to decline payment, the "recipient" must acknowledge the following:
        - **Future Acceptance of Stipend Payments – t**he recipient reserves the right to change their decision and accept stipend payments for any future study visits. Should they choose to do so, the recipient must notify the research team in writing.
        - **Accrued Stipend Payments –** Understand that the recipient may choose to accept previously accrued stipend payments that have not yet been disbursed at a later date.
        - **IRS Reporting Implications –** Acknowledge that if the recipient collects these previously accrued payments, the total sum received may necessitate reporting to the IRS, which might not have been required had the participant accepted the payments incrementally.
        - **Deadline for Collection –** Understand that the recipient can claim these accrued payments up to one month after the completion of the study or my participation in the study, whichever occurs last.

- **Non-Payability in Event of Death:** In the event of the recipient's death, any previously accrued payments will not be payable to the recipient's heirs and/or estate.

ii. The decision to decline and later decision to accept payment must be documented in the project's financial records as these records are not to be shared with Sponsors/CROs. A template for documenting the decision to decline payment can be found on the CTO Infonet site.

2. Stipend
    a. Considered reportable income by IRS.
    b. The party that disperses payment shall manage 1099 reporting to the participant and IRS.
    c. The amount of the stipend should be reflective of the following while not asserting undue coercion:
        i. Time and effort required at the visit,
        ii. Frequency of visits,
        iii. Level of inconvenience and discomfort experienced**,**
        iv. Activities completed,
        v. Length of participation in the overall study.
    d. The amount of a stipend may vary based on the visit, activities, and/or sub-studies complete.
        i. The amount may be reduced for virtual/remote visits to reflect the decrease in time and effort required at the visit and the activities completed **on the condition that the consent document *explicitly* denotes the change in the amount received.**
    e. Study completion incentive payments may be given provided that such incentive is not coercive.
        i. The entire payment may not be contingent upon completion of the entire study, unless the following the conditions are met:
            - There are no other payments except for the incentive payment.
            - The duration of entire study is deemed by the IRB to be of such a significant short duration and of such few activities that it is impracticable to assign a value to each activity and the study would not benefit from a partial data set.
        ii. The IRB will be the ultimate arbiter if the amount of an incentive payment paid as a bonus for completion is reasonable and not so large as to unduly induce participant to stay in the study when they would otherwise have withdrawn.

3. Travel
    a. Generally considered by the IRS to be exempt from reporting.
    b. Travel can be reimbursed for actual costs, flat rate reimbursement, or a hybrid model.
        i. Actual Costs - participant and/or caregiver provide receipts for actual expenses incurred.
            - Receipts provided for gas, tolls, etc.

- Mileage paid based on the IRS's Standard Business Mileage Rate using an Internet map (e.g., Google Maps, etc.) showing distance between home and investigative site.

ii. Flat Rate Reimbursement - all participants and/or caregivers are given a flat (or set) amount.

iii. Hybrid Model - participant and/or caregiver is given a flat amount if their home is within a certain distance of the investigative site or documentation of mileage and receipts is provided for actual expenses.

- Participants and/or caregivers not wishing to provide receipts and/or their address may claim the flat rate.

c. Reimbursement for travel is not provided for routine care hospitalizations where the admission occurred prior to the participant igning consent (i.e., an index event allowing a patient to become eligible for a study, or an unrelated event to the condition or disease being studied).

i. Travel may be offered to routine care outpatient visits if the intention is to remove financial barriers so that the participant can arrive on-site so that all data points may be collected and ensure that the visit occurs within the protocol defined windows.

ii. Research visits designated as "Routine Care" in the coverage analysis review may cause undue financial hardship on participants who come to the Institution only for their participation in the clinical research. Therefore, it would create equity to offer travel reimbursement to all participants.

4. Other expense reimbursement

a. Other expenses (e.g., meals, lodging, etc.) may be deemed appropriate for a study, on a case-by-case basis, to provide reasonable reimbursement to remove financial barriers that would hinder a participant from returning to the site for visit and does not cause undue coercion or influence on the participant and/or caregiver.

RELATED POLICIES AND REFERENCES

Code of Federal Regulations: General Requirements for Informed Consent (45 CFR 46.116)

Information Sheet: Payment and Reimbursement to Research Subjects; Guidance for Institutional Review Boards and Clinical Investigators; U. S. Food and Drug Administration; January 2018

International Conference on Harmonization Good Clinical Practice E6(R2)

Penn State University Policy: Payments to Human Participants in Research (RPG03)

Penn State University Institutional Review Board Standard Operation Procedure: Written Documentation of Consent (HRP-091)

Penn State University Institutional Review Board Standard Operation Procedure: Informed Consent Process for Research (HRP-090)

Documentation of Informed Consent Process (CR-301)

Clinical Trials Office Infonet (https://infonet.pennstatehershey.net/web/clinical-trials-office)

Clinical Research Guidebook (https://research.med.psu.edu/research-support/guidebook/)

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