

Standard Operating Procedure (SOP)

SOP number: SOP CW AHC 250	SOP Name: Research Participant Remuneration
Location: *Company-Wide Policies	Responsible Department: Research Finance
SOP Owner/Executive Owner: Director,	Original Creation Date 7/1/2022
Research Finance	
Effective Date 08/22/2022	Review Date 8/17/2022

- I. <u>SCOPE</u>: This standard operating procedure (SOP) applies to all employees and agents of AdventHealth.
- **II. <u>PURPOSE</u>:** This SOP describes the procedures, internal controls, and confidentiality of information for the establishment and use of Greenphire ClinCard Payment for approved AdventHealth payment programs.
- III. **QUALIFIED PERSONNEL:** HRPP Personnel and Research Personnel.
- IV. TRAINING: Not applicable
- V. SUPPLIES & EQUIPMENT: Not applicable

VI. <u>PROCESS/PROCEDURE</u>:

A. Remuneration to Participants in Human Research

- 1. The Institutional Review Board (IRB) is responsible for the protection of the rights and welfare of participants in Human Research. This includes ensuring that any payment or Remuneration offered to research participants is fair and does not include undue inducement.
- 2. All proposed Remuneration, including all amendments, to Human Research will be reviewed in accordance with HRP-403 WORKSHEET Payments and must be approved by the IRB prior to implementation.

B. Internal Revenue Services (IRS) Reporting Requirements

- AdventHealth is responsible for complying with IRS requirement for all payments made which fall under the reporting regulation and CW F 85.5 Information Returns (Form 1099) policy, the following must be completed:
 - a) Obtain a completed and signed W-9 from participants in Human Research receiving payments, regardless of the amount, from AdventHealth.
 - b) For all research-related Remuneration, excluding Reimbursement, made to nonemployees, a Form 1099 will be issued to the non-employee by AdventHealth or its agent.
 - c) For all research-related Remuneration, excluding Reimbursement, made to AdventHealth employees, the research-related Remuneration will be reported in the employee's form W-2, Wage and Tax Statement.
- 2. The informed consent document for all studies that involve Remuneration shall disclose these IRS compliance requirements in a manner approved by the IRB.

C. Remuneration Options

- 1. Greenphire ClinCard Payment
 - a) A reloadable prepaid card or a virtual card available to AdventHealth and is the
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preferred payment option for most Human Research that will provide Remuneration.

- b) Access to the Greenphire ClinCard Payment system is restricted to AdventHealth authorized users. Please contact Research Finance at <u>CFD-</u> <u>S.Research,Finance@AdventHealth.com</u> for inquiries regarding use of the system.
- 2. Non-Monetary Remuneration: Non-monetary Remuneration should be monitored to ensure compliance with applicable reporting requirements. It should be tracked per recipient with an estimated value for the item(s).
- Other Remuneration Options: In some cases, the study team may not be able to utilize Greenphire ClinCard Payment. Please contact the Research Finance at <u>CFD-</u> <u>S.Research.Finance@AdventHealth.commailto:</u>.
- 4. Sponsored-Provided Remuneration
 - a) Should the study sponsor provide other forms(s) of Remuneration such as gift cards, non-monetary items, etc., the study team will follow instructions provided by the sponsor.
 - b) IRS reporting requirements for such Remuneration method is the responsibility of the sponsor.

VII. <u>DEFINITION(S)</u>:

Greenphire ClinCard Payment: Reloadable card (physical or virtual), instant-issue, stored value cards with multiple redemption options.

HRPP Personnel: Individuals involved in the oversight of human subjects research.

Human Research: Any activity that is Human Research as Defined by HHS or Human Research as Defined by FDA.

Monetary Remuneration: Cash equivalent payment options such as cash, gift cards, vouchers, etc.

Non-monetary Remuneration: Gifts, promotional items, other tangible items, etc.

Reimbursement: Refers to payment of actual travel expenses (e.g. parking, mileage, tolls, hotel, etc.)

Remuneration: Payment including Reimbursement, which may be monetary or nonmonetary, for participation in research.

Research Personnel: Investigators and other individuals involved in the design, conduct, or reporting of research.

- VIII. **EXCEPTION(S)**: Not applicable
- IX. <u>REFERENCE(S)</u>: Not applicable

X. <u>RELATED DOCUMENT(S)/ATTACHMENT(S)</u>:

- CW AHC 108 Human Research Protection Program
- CW AHC 251 Greenphire ClinCard Payment

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Greenphire ClinCard Payment

- WORKSHEETS are located on the AdventHealth Research Institute website
 O HRP-403 WORKSHEET Payment
- CW F 85.5 Information Returns (Form 1099)

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