
**WEST VIRGINIA
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE**

(1.11) Human Subject Payment Overview

The West Virginia Clinical & Translational Science (WVCTSI) Institute engages in human subject research and provides payment to study participants in recognition of their valuable contributions. WVCTSI has established processes for issuing payment for basic and clinical research participation. This Standard Operating Procedure (SOP) establishes the tax reporting requirements and data-security protocols related to the payment of human subjects participating in WVCTSI supported research. Investigators conducting WVCTSI research studies that compensate human subjects must collect and document all personal information necessary to comply with IRS tax-reporting regulations. High-risk confidential information must only be collected when necessary per this policy; any confidential information collected must be protected in accordance with the University's Enterprise Information Security Policy.

Purpose

The purpose of this operating procedure is to provide guidelines to WVCTSI investigators when providing payment to research subjects. With appropriate Institutional Review Board (IRB) approval and proper consent documentation, it is allowable for subjects to be paid for their participation in research. To assure that either are coercive or present undue influence, the amount of the payment and the proposed method and timing of disbursement must be reviewed and approved by the IRB.

Scope

This procedure applies to all WVCTSI directors, Core chairs, investigators, chairs, vice-chairs, scholars, investigators, staff, core constituents and partner sites conducting research in any way supported by the WVCTSI.

Clarification

The preferred method of payment for human subject participation is via gift card. For WVU investigators, gift cards should be purchased utilizing the West Virginia University state procurement card (P-Card) or the WVU Research Corporation procurement card. For an overview of the WVU process, please refer to <http://financediv.wvu.edu/r/download/189408>. All investigators at partner institutions should follow their respective policies regarding the purchase of gift cards.

All gift card purchases must be pre-approved prior to purchase. The WVCTSI investigator will be responsible for securing her/his own P-Card; if the investigator has any questions regarding the type of P-Card needed for expenditures, she/he may contact the Director of Research Administration.

Definitions

Human subject: A volunteer participant in a research study. Any person participating in a research study is known as a human subject (participant). Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: 1) data through intervention or interaction with the individual or 2) identifiable private information.

Human subject payments: Payments made to individuals for their participation in research projects or reimbursements for expenses.

Taxability: If WVCTSI pays \$600 or more to a US tax resident during the calendar year, then WVU is required to report the payments to the IRS and issue the recipient a Form 1099. Payments to foreign nationals are reported on a Form 1042-S. Where reporting is required, the WVCTSI investigator must collect the recipient's full legal name, SSN/ITIN (or HUID), permanent address, mailing address (if different), and Foreign National Information Form (FNIF; for foreign nationals).

Principal Investigator (PI)/Investigator: the person in charge of conducting a research study with human subjects as participants.

Chairs/Vice-Chairs: persons named as leaders of WVCTSI core activities

WVCTSI Staff: staff members reporting to the WVCTSI cores

Core Constituents: a member of a WVCTSI core who participate in the activities of the institute

Scholar: a person who develops and conducts mentored, clinical and translational research for WVCTSI

Partner Sites: WVCTSI staff members at Charleston Area Medical Center and School of Osteopathic Medicine who are named within the WVCTSI grant and contribute effort.

Policy

WVCTSI permits human research subject payments as remuneration for participation in research studies. With appropriate IRB approval, the preferred human research subject payment is to be made via gift card (preferred) or by a check issued through the WVU Office of Sponsored Programs.

If unable to purchase gift cards, the WVCTSI investigator should contact the Director of Research Administration for discussion and subsequent approval of alternative form(s) of payment.

Each investigator will be responsible for maintaining detailed record of all research subject payments. **Use of personal funds for research participant payment is strictly prohibited.**

Procedures

Gift Card Purchase via Procurement Card

For WVU WVCTSI investigators, the process for purchasing gift cards as the form of human subject payment is as follows:

Please remember that gift cards cannot be purchased with your PCard unless approved in advance by PCPS PCard Administration. To request approval, please email the following information to PCardAdministration@mail.wvu.edu:

1. Cardholder's name.
2. Is this on a State or WVURC PCard?
3. Last six digits of the PCard number.
4. Vendor's name.
5. Dollar amount.
6. Number of gift cards.
7. Description of what is being purchased.
8. Business purpose for transaction.

Please note: all State funded requests will also require approval from the WV State Auditor's Office. For these requests, PCard Administration will forward your request to the Auditor's Office. Following review, PCard Administration will notify you via email regarding the approval of your request. A copy of the email approval from WVU PCard Administration and the WV State Auditor's Office (if applicable) should be kept with the transaction documentation.

Things to Remember:

- If your transaction is grant-funded, please verify the purchase is allowed for by the granting agency prior to payment.
- Gift cards cannot be given to employees for employee recognition.
- If an individual receiving a gift card is also an employee (i.e. participated in a study, but also an employee), please note that this expense may be tax reportable.

Required documentation of payment with gift card

Each WVCTSI investigator is responsible for maintaining detailed records of all research subject payments. The Research Subject Payment Log (example attached) must include:

- Protocol title and number
- Principal investigator
- Value of the gift card
- Type of gift certificate/card (e.g. Visa)
- Unique identification code shown on the gift card
- Subject's name and study number
- Datecard issued

The subject must sign and date the log to show receipt of the gift card.

Required process if paying subject by check

If patient will be paid by a check, the subject must sign a prepared Vendor's Invoice form (attached) and submit it to their department accounting office for processing.

In the event of an IRS or sponsored programs audit, it will be the joint responsibility of the PI/investigator and the related local finance office to supply all required supporting documentation for human subject payments made from the PI/investigator's accounts. PIs/investigators must securely maintain confidential study data needed to support payments to recipients. Both WVCTSI and the investigator administrative unit must retain supporting documentation through at least June 30, 2020.

Roles and Responsibilities

Principal Investigators are responsible for abiding by this policy and its accompanying procedures. In the event of an audit, it will be the joint responsibility of the investigator and the local EBO to supply all required supporting documentation for human subject payments made by WVCTSI investigator awards.

The responsibility for interpretation of this policy rests with the Director of Research Administration.

References and Authority

The cost principles are set forth in the following documents and are incorporated by reference in 45 CFR parts 74.27 and 92.22. As noted below, OMB Circulars A-21, A-87 and A-122 have relocated to Title 2 in the Code of Federal Regulations (2 CFR) :

- OMB Circular A-21 (relocated to 2 CFR 220) — Cost Principles for Educational Institutions.
- OMB Circular A-87 (relocated to 2 CFR 225) — Cost Principles for State and Local Governments and Indian Tribal Governments.
- OMB Circular A-122 (relocated to 2 CFR 230) — Cost Principles for Non-Profit Institutions. Larger non-profit organizations that are specifically listed in Attachment C to OMB Circular A-122 are subject to the Federal cost principles applicable to commercial organizations (48 CFR 31.2) rather than to the cost principles for non-profit organizations.
- 45 CFR 74, Appendix E — Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals.
- 48 CFR 31.2 (Federal Acquisition Regulation) — Contracts with Commercial Organizations.
- WVU Administration and Finance Policies including Payroll & Tax, Financial Services, and Business Services located at: <http://adminfin.wvu.edu/policies>

Approval and Authority to Proceed

I approve the project as described above, and authorize to proceed.

Name	Title	Date
Sally L. Hodder, MD	Director, West Virginia Clinical and Translational Science Institute	5/3/16



Approved By

5/3/16
Date