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|  | | **POLICY TITLE**  **Compensating Volunteers Who Participate in Clinical Research** | | | | | |
| **POLICY #** | **VERSION** | **CATEGORY** | | **SUB-CATEGORY** | | | |
| 11370 | 1.0 | Organizational | | Choose a Policy Type. | | | Medical Staff Only -Choose a Policy Type |
| **KEY WORDS**  **Research, Compensation, Payment** | | Divisional | | Research | | | Choose a Policy Type |
| Departmental | | Rebecca D. Considine Research Institute | | | Choose a Policy Type |
| **CURRENT EFFECTIVE DATE:** 7/25/2019  **LAST APPROVAL DATE:** N/A  **ORIGINAL DATE:** 7/25/2019 | | | | **THIS POLICY REPLACES:**  **N/A** | | | |
| **APPLICABILITY:**  Akron Children’s Hospital & Affiliates ACH Foundation  Children’s Home Care Child Dimensions Insurance Company | | | | | | | |
| **Contact Person/Position: Michelle Jacobs, IRB Coordinator** | | | | | | **Pages: 3** | |
| **SPECIAL REVIEW** | | | | | | **ADMINISTRATIVE REVIEW** | |
| Environment of Care/Safety | | | Medical Staff | | | Administrative Staff | |
| Health Information Management | | | Nursing Guidelines | | | Board of Directors | |
| Human Resources | | | Patient Services | | | Interdisciplinary Care Committee | |
| Infection Control | | | Pharmacy & Therapeutics | | | Medical Staff Executive Committee | |
| Information Services | | | Radiology | | | Research | |
| Laboratory/Pathology | | | Click here to enter text. | | |  | |
| **REFERENCES AND ACCREDITATION STANDARDS:**  Click here to enter text. | | | | | | | |
| **APPROVAL**  **James Brazeal, JD**  **Vice President, Research Administration** | | | | | **APPROVAL**  Click here to enter text.  **Click here to enter Title of Authorized Representative** | | |

Original signature on file in Clinical Research

**PURPOSE:**

The purpose of this policy is to establish uniform guidelines at Akron Children’s Hospital (ACH), for allowable forms of compensation to research participants, and required management and disbursement of payments.

**POLICY:**

Any plan for compensating volunteers who participate in research must be approved by the ACH Institutional Review Board (IRB) or by the IRB of Record, when study oversight has been ceded to an external IRB. Acceptable methods of payment to participants are individual gift cards or loadable debit cards (e.g., clincards). Payments to participants cannot be used by the participants to offset any outstanding receivable balance they may have with ACH.

The Research Finance coordinator will implement proper controls to account for all funds disbursed to research participants; any Principal Investigator whose study is approved for compensation to subjects must keep an accounting of available funds as described in the Procedure section of this policy. This accounting is to be made available upon request for audit purposes.

All payments discussed in this policy are subject to requirements established by the Internal Revenue Service (IRS), which requires that all payments to individuals, including payments to research subjects, be reported on an IRS 1099 form, if they equal or exceed the current IRS reporting threshold.

**Non-compliance** with this policy will be subject to disciplinary action up to and including termination

**Definition:**

**Form 1099:** the official form used by the Internal Revenue Service to report various types of income other than wages.

**PROCEDURE:**

**Payment by gift cards.** Gift cards can be used to pay research participants for projects for which the total amount paid to each participant by that project does not exceed $100. Gift cards are considered “cash or cash equivalents” and are subject to ACH’s Cash Handling policy [#11001].

**Payment by debit cards:**

Debit cards are recommended for single payments of $20 or more, or when multiple payments are made across the period of study participation. The Research Finance office will create the study account with the card vendor. The PI or designee will enter requests for individual debit cards and enter the amount to be loaded.

**Study participants who are ACH employees:**

The value of cash payments or gift cards issued to employees must be reported to the Payroll Office. An email including the employee’s name, employee ID and value of the gift card should be sent to [payroll@akronchildrens.org](mailto:payroll@akronchildrens.org).

**Controls:**

Regardless of the payment method used, the research study team will implement controls to safeguard the

funds. Such controls must include the following:

* + All payments by gift/debit cards are subject to this policy and must be monitored routinely.
  + For gift cards, an inventory log of all cards must be maintained. The log must list the card numbers along

with date of purchase, date of disbursement and by whom, as well as the recipient and amount. This listing must be kept in a separate location from the actual cards. A sample log is attached to this policy.

* + For debit cards, an inventory of all cards must be maintained. The log must list the card numbers along with the date assigned, date distributed, and the recipient. Amounts loaded on the card must be recorded with the date loaded (insert new row to record subsequent amount/date).
* Withdrawals of cards require a dual signature on the inventory log.
* A study log must be maintained for each project, identifying the project name, IRB protocol number, transaction date, study participants and payments made to them. A sample log is attached to this policy.
* All gift cards must be purchased through purchasing. A Request for Payment is processed by the Research Finance office and submitted to Accounts Payable.
* The use of generic gift cards is encouraged. Imprinted holiday, animal, and other themes are not allowed.
* The PI/designee will determine the number of cards needed and the length of the study. The number of cards purchased with sponsored funds must be kept to a minimum to cover the immediate needs. It is recommended that this quantity does not exceed one month’s supply of gift cards needed for the study.
* At the end of a study, the cost of any unused gift cards will be transferred to the cost center and the cost of the gift cards will be reimbursed by the cost center to the sponsored project. Unused cards that are transferred to the home accounting unit are still property of ACH and can only be used to fund normal operating expenses (such as supplies) in accordance with the department's operating budget. The department must maintain a log of all cards and is subject to random audits. When unused gift cards transferred to the cost centr cannot be used to fund normal operating expenses (e.g., gift cards from restaurants or gas stations), these cards must be donated to an ACH charity event. The cost for these cards must be absorbed by the cost center.
* When gift cards or funds held for study participants cannot be accounted for, the PI or Study Team member will contact the offices of Research Integrity and Research Finance immediately upon discovery of the missing funds. The PI will be required to provide these offices with a corrective action plan, describing the controls that will be implemented to prevent similar problems from happening again and reimburse the project for the value of the missing cards or funds. Reimbursement cannot be made from other sponsored projects.
* Complete the Study Participant Account Reconciliation Form. This form must be completed as soon as all gift cards have been distributed, but by no later than the closeout of the sponsored project.

**SCOPE/RESPONSIBILITY:**

The **Principal Investigator** is ultimately responsible for all funds disbursed under this policy; however, he/she may delegate custodial functions of the funds to a Study Team member. Delegated authority must be recorded on the study delegation log and acknowledged by the Study Team Member.

**PI or Designee must:**

* For gift cards, maintain an inventory listing of all cards and keep this list in a separate location from the cards.
* For gift cards issued to ACH employees, email the Payroll Office ([payroll@akronchildrens.org](mailto:payroll@akronchildrens.org)) the employee’s name, employee ID and the value of the gift card.
* Maintain a study disbursement log that includes the date, participant name or ID, study IRB number and the value of the card.
* Store gift cards in a locked drawer, box or cabinet, in a locked area.
* Provide Research Finance with a Study Participant Account Reconciliation Form within thirty days of the termination of the project.
* Reimburse the project immediately for any unused gift cards.

**Research Finance must:**

* Review the Study Participant Account Reconciliation Form and contact the [??] if there are any unresolved balances or variances.
* Close out the project in accordance with the [policy]

**Audits:**

In addition to the required monitoring by study staff, the offices of Research Finance and Research Integrity may perform routine or for cause audits of studies that are compensating subjects via gift or debit cards.