



Department of Pediatrics

Section: Administration	Effective Date: 07/12/2016
Title: Additional Guidelines for Cash or Gift Card Patient Stipend Funds	Version number: 1.1

I. Purpose:

These guidelines, in keeping with Emory University’s comprehensive approach to research integrity, are intended to outline the additional processes specific to the Department of Pediatrics for procuring, storing, tracking, disbursing, auditing, and closing out patient stipend funds (in the form of cash or gift cards) for human research study participants. This document applies to any funds that are managed by Department of Pediatric staff members and does not include those sent from the University or Sponsor directly to the patient. These guidelines are supplemental to Emory University Policy 7.28: Payments to Human Research Study Participants.

II. Revision History:

Date	Revision Number	Modification
07/12/2016	1.1	Study staff other than custodians may disburse PSF, waivers may be granted if patient signature is not obtainable.
07/01/2016	1.0	New policy and procedure

III. Definitions

Custodian - Custodians are Emory employees, who support the management of human research studies on behalf of a PI. PIs may choose to appoint themselves as custodians. Students, contractors, temporary employees, or employees of partner organizations may not serve as custodians.

DOP – Department of Pediatrics

Emory Children’s Center Research Unit (ECC-RU) – an Emory University space dedicated to research subject visits for IRB approved studies. There are 2 exam rooms, 1 consult room and a badge access research staff work room. It is located on the first floor of the Emory Children’s Center (2105 Uppergate Drive, Atlanta, GA 30322).

DOP Finance Management staff member – a DOP employee with a finance or accounting role within department administration.

Gift Card – a card having monetary value issued by a retailer or bank to be used as an alternative to cash.

Institutional Review Board (IRB) – A research oversight committee charged with assuring that, both in advance and by periodic review, appropriate steps are taken to protect the rights and welfare of humans participating as subjects in approved research studies.

Patient Stipend Funds (PSF) - payments distributed to human research study participants to compensate for the time and effort required for a research project.

Principal Investigator (PI) – a person (including Project Principal Investigators, Co-Principal Investigators, and Co-Investigators) who is responsible for the design, conduct or reporting of the research project or proposed research project.

Research Participant Payment Fund (RPPF) – A cash fund established to provide payments to human research study participants for their time and effort and expenses incurred as a result of participating in the study

IV. Persons Affected:

This policy applies to all administrators and custodians of human research studies within the Department of Pediatrics who provide payments to participants or subjects for either: a) expenses incurred as a result of participation (e.g., travel related costs); or b) payments to compensate participants for their time and effort in the research study, in the payment form of cash or gift cards.

V. Policy and Procedure Details

The policy describes the following areas:

- Procuring
- Storage
- Tracking
- Disbursing
- Auditing
- Close out

Procuring

There must be a separation of duties between requesting and approving the procurement of patient stipend funds. A minimum of 1 primary and 1 alternate custodian must be designated for every study utilizing PSF.

- Gift cards, for the use of PSF, must be purchased by a DOP Finance Management staff member. Complete the “*DOP PSF Gift Card Request Form*” and submit to DOPStipends@emory.edu. **Note – the Emory Express system is configured so that a person cannot create and approve the same requisition.**

- Cash is obtained by completing the Emory University RPPF forms. Please see www.finance.emory.edu to link to specific instructions. **Note – the RPPF process is configured so that a person cannot create and approve the same requisition.**
- If gift cards are provided directly to Emory by a sponsor, complete the “DOP PSF Sponsor-Provided Funds Form” and submit to DOPStipends@emory.edu.

Storage

All cash or gift cards used to compensate research subjects must be kept in a secure location at all times. No funds may be accepted until a secure location has been established. A secure location is defined as:

1. Kept in a safe
AND
2. The safe is located behind a locked door, with minimal or monitored access

For Emory main campus, there is a secure location available in the ECC-RU Workroom. A safe can be checked out by contacting DOPStipends@emory.edu.

If you already have a secure location as defined above, contact DOPStipends@emory.edu so that a visit can be scheduled to document and verify.

If a PI is not conducting research on Emory main campus and does not have access to a secure location, the department Finance Management staff member must be notified (DOPStipends@emory.edu) and the department will assist in creating a secure location for storage.

Tracking

A distribution log must be kept documenting the funds disbursed. Minimum information required:

- Smartkey and project number for the source of funds (both found on the Emory Notice of Award)
- 2 forms of study identification (Study Title, protocol number, IRB number, Sponsor, etc)
- 1 additional identifier for gift cards (gift card number, access code, PIN number, etc)
- Name of PI
- Name of research staff performing the transaction
- Unique participant ID (name or Study ID)
- Transaction details (date, amount, type of funds)

A sponsor-provided log may be used and appended if needed to contain the minimum information.

Disbursing

There must be documentation of the participant receipt of the funds. Minimum information required:

- 2 forms of study identification (Study Title, protocol number, IRB number, Sponsor, etc)
- Name of PI
- Name and signature of research staff performing the transaction
- Name and signature of participant receiving funds*

- Transaction details (date, amount, type of funds)

One copy should be given to the participant and one copy maintained by the custodian. A receipt book may be utilized for this process.

*If a patient signature cannot be obtained due to the nature of the study, the Department may grant a waiver.

Audits

In addition to potential audits by the University, Department of Pediatrics Administration will randomly audit gift cards or RPPF cash. Upon a request, the PI must produce the required supporting documents and access to the funds. The Department audit will be performed by two DOP Finance Management staff members who are not involved in the daily management of PSF.

Close out

Once a study has completed and no further PSF will be disbursed, the study team must meet with a DOP Finance Management staff member for a final accounting of the PSF, to include review of logs and a count of any remaining funds. The “DOP PSF Close Out Form” must be completed and submitted to DOPStipends@emory.edu within 2 business days of study closure. Per current Emory processes, cash and/or any unused cards will need to either be returned for credit or transferred to a discretionary account.

VI. Related Links and Documents

Policy 7.28

Payments to Human Research Study Participants <http://policies.emory.edu/7.28>

Policy 2.110

Approval Requirements for Reimbursements and Payments <http://policies.emory.edu/2.110>

Policy 2.113

Institutional Fiscal Responsibility Framework <http://policies.emory.edu/2.113>

Policy 2.114

Fiscal Transactional Roles and Responsibilities <http://policies.emory.edu/2.114>

Policy 2.121

General Purchasing Policy <http://policies.emory.edu/2.121>

Institutional Review Board: <http://www.irb.emory.edu>

Emory Department of Finance: <http://www.finance.emory.edu>

VII. Contact Information

Subject	Contact	Phone	Email
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Clarification of this document			DOPstipends@emory.edu
Clarification of RPPF submission	Controller's Office		rppf@emory.edu
ECC-RU workroom badge access			ECC-RU@emory.edu

VIII. Related documents

The following documents can be found at <http://www.pedsresearch.org/research/resources/clinical-research-resources/research-coordinator-resources/patient-stipend-funds/>:

- DOP PSF Gift Card Request Form*
- DOP PSF Sponsor-Provided Funds Form*
- DOP PSF Tracking Log template*
- Patient Stipend Disbursement Form template*
- DOP PSF Close Out Form*