



Policy Statement

This policy establishes the options for research study participant payment, including advances and replenishment of research funds, to facilitate human subject research.

Roles and Responsibilities

Principal Investigator (PI) – is responsible (either directly or via an appointed study coordinator or other designee) for:

- Maintaining Institutional Review Board (IRB) approval for duration of study;
- Safeguarding the research funds prior to distribution;
- Issuing individual payments to study participants as either checks, cash or gift cards/certificates;
- Securing appropriate documentation for each study participant payment acknowledging financial distribution;
- Reconciling advanced and replenishment funds annually.

Sponsored Program Accounting (SPA) – is responsible for the oversight of study participant payments from research funds and maintaining study participant confidentiality during research-related financial transactions.

Policy

1. IRS Regulations - The Internal Revenue Service (IRS) requires study participant payments aggregating \$600 or more paid to an individual during a calendar year to be reported on Form 1099-MISC, Miscellaneous Income. A W-9 Tax Identification Form should be completed by designee for payments in a calendar year aggregating \$600 or more.
2. There are two methods of paying study participants. The Principal Investigator may select the method most appropriate for each human subject study.
 - Preferred Payment Method: The preferred method is to request that Sponsored Program Accounting send a check directly to the study participant. A W-9 should be submitted with the check requisition. This method allows financial verification that the participant has received the check, using the signature on the cashed check.
 - Alternative Method: The alternative method allows a principal investigator to request an advance of research funds (for an estimated two months of participant reimbursement). This one-time advance is to be used to open a bank account for the exclusive use of

research funds for study participant payments. This bank account will be opened under the principal investigator's name and will not be affiliated with Loyola University. It is strongly recommended that a department administrator or similar designee be a co-signatory on the research account. Monthly (including annual) reconciliation will require bank statements to be supplied to SPA.

The next portions of this policy relate ONLY to the Alternative Method of participant payment.

3. Methods of Participant Payment - The research team may use the research funds to pay study participant using checks, cash or gift cards/certificates. Regardless of the specific mechanism of payment, the research team must supply to SPA adequate documentation of payment receipt by the study participant. The method of payment to the subject must be consistent with the financial information as recorded on the IRB Informed Consent Form. Using negotiable items, such as gift card/certificates, requires very strict accountability as they are cash equivalents which must be treated like cash.
4. Documentation of Payment Distribution - Adequate documentation of financial distribution consists of the IRB# of an approved study, the unique participant study number as well as proof of study participant payment by:
 - Research study participant signature OR
 - Research team member (coordinator or appropriate designee) signature witnessing participant payment for studies where participant confidentiality needs are extreme. Only the PI and designated research staff should be able to link the study subject number to the individual study participants.
5. Request for Replenishment Funds - After SPA receives complete documentation of financial disbursements, replenishment funds will be released. Complete documentation consists of a check requisition, Fund Replenishment Documentation Form, and pertinent bank statement. Replenishment funds are to be deposited into the established bank account for continued support of the approved research.
6. Reconciliation of Advance and Replenishment Funds – Upon receipt of complete documentation for replenishment, disbursements will be charged to grants as expenses. Advances on an accounting unit must be reconciled monthly. Unused funds at the close of the study must be returned for re-deposit into the SPA research account.
7. Periodic Audit – Advance and replenishment funds made payable to the PI are subject to higher scrutiny by the Federal authorities and as such, an annual audit of the receivable will be done to ensure the general ledger contains updated and accurate information.

Applicable Forms:

Advance Fund Establishment Form (AFE) (Account 5XXXXXX-1271)
Fund Replenishment Documentation (Account 5XXXXXX-6585)



Advance Fund Establishment Form (AFE)

Principal Investigator: _____

IRB Number: _____

Accounting Unit: _____ 5 - 1271 _____ (Advance Payment Receivable)

Program Title: _____

Project Start Date: _____

Budget Start Date: _____

Project End Date: _____

Budget End Date: _____

Approx # of Monthly Subjects: _____

Cost Per Visit: _____

Anticipated Monthly Amount: _____

Initial Advance Request: _____ (Maximum advance is for two month period)

Personnel Authorized to Handle Advance Funds:

Printed Name

Signature

Printed Name

Signature

Printed Name

Signature

I hereby certify that the above information is correct to the best of my knowledge and have read and understand my responsibilities as Principal Investigator as outlined in the Advance for Payment to Study Subject Policy.

PI Signature Date

Additional Information:
1) AFE Form must be attached to a check requisition
2) AFE Form must be completely filled out to be processed



Fund Replenishment Documentation

Preparing people to lead extraordinary lives

Principal Investigator: _____

IRB Number: _____

Accounting Unit: 5 - 6585 (Study Participant Expenses)

Program Title: _____

<u>Study Subject Number</u>	<u>Date of Visit</u>	<u>Amount</u>	<u>Witness Signature</u>
1)			
2)			
3)			
4)			
5)			
6)			
7)			
8)			
9)			
10)			
11)			
12)			
13)			
14)			
15)			
16)			
17)			
18)			
19)			
20)			
		<u>\$ 0.00</u>	

PI Signature