

## PAYMENTS TO RESEARCH SUBJECTS

### Clinical Research Policy/Procedure

**Approved:** December 2007

**Next Review:** December 2010

#### Purpose:

To provide compensation for individuals who volunteer in research conducted at the Swedish Research Center (SRC) for their time and effort and/or other reimbursable expenses. To protect the rights of research subjects by assuring the informed consent of research subjects is free from coercion and undue influence. To provide institutional procedures for compensating research subjects.

#### Responsible Persons:

Investigators, SRC Research Coordination Staff, and SRC Grants & Contracts Staff.

#### Definitions:

**Subject Stipend** is a payment in cash or cash equivalent provided to research subjects for reimbursement of their time and effort or other reimbursable expenses when volunteering in research. Examples of stipends include cash, checks, and gift certificates/cards.

**Recruitment Incentive** is any good, regardless of value, provided to a research subject free of charge or under circumstances where the research subject would not receive the good as a normal part of medical care. Examples of recruitment incentives include free medication supply, free medical devices, t-shirts, tote bags, water bottles, coffee mugs, blankets, portable coolers, or other goods or study materials that are not required to be returned by the subject at the conclusion of the research study.

### Policy

Payments may be provided to research subjects volunteering in research studies conducted at the SRC. Payments to research subjects should be for the purpose of reimbursing individuals for their time, effort, and expenses associated with participating in a research study. Payments to research subjects are not considered a benefit of participating in research and should not be construed to research subjects as such.

Federal regulations require investigators to obtain the voluntary informed consent of subjects and seek consent only under circumstances that minimize the possibility of coercion or undue influence. When compensation will be made available to research subjects, investigators and research staff should be aware of the coercive effect compensation may have on a prospective research subject's decision to volunteer for a research study.

Payments to research subjects for participation in research, including *stipends* and *research incentives*, must be reviewed and approved by the Institutional Review Board (IRB) before it may be offered or provided to subjects. IRB review should aim to assure that payments to research subjects are not coercive and will not present an undue inducement that may affect a prospective research subject's voluntary choice to participate in a research study.

## Procedure

### GENERAL GUIDELINES FOR PAYMENTS TO RESEARCH SUBJECTS

1. Payments to research subjects are comprised of all forms of remuneration provided to subjects including *subject stipends* and *recruitment incentives*.
2. If an investigator intends to pay research subjects for participating in a research study, the payments must be available to all participating research subjects. Unless justifying circumstances exist, the amount, schedule and method of payments should be the same for all research subjects.
3. Payments may not be of an amount that potentially could coerce or unduly influence research subjects to participate (or continue participation) in a research study. The amount of payment offered to research subjects should be economically consistent with local community standards. The investigator should also consider the prospective research population's vulnerability to coercion or influence (e.g., economically-disadvantaged persons, children).
4. Payments must be reasonable in relation to the time and effort expended by the research subjects. Payments may correspond to the complexity of the research study (e.g., type and number of procedures), the time/duration of the research study (e.g., overnight visits), and/or anticipated discomfort or inconvenience to the subjects (e.g., diet restrictions).
5. Payments to research subjects must be proportionally distributed over the course of a research study (i.e., prorated). For example, payments may be provided sequentially on a study milestone basis. With few exceptions, payments to research subjects may not be contingent upon study completion (e.g., exception for research studies involving one study visit). A study completion bonus/incentive of small proportion may be provided to research subjects if approved by the IRB.
6. An investigator may not offer reimbursement for Medicare co-payments (considered Medicare fraud) unless the arrangement is pre-approved as part of a federal trial.
7. Sponsors of commercial and federally-funded research studies should be made aware of any amount the investigator intends to reimburse research subjects. To protect the confidentiality of research subjects, sponsors must agree to provide remuneration directly to an investigator site for distribution to research subjects. Sponsors may not provide remuneration directly to research subjects.

### IRB REVIEW OF PAYMENTS TO RESEARCH SUBJECTS

8. **A proposal to pay research subjects for participation in research must be reviewed and approved by the IRB before payments may be offered or provided to**

**subjects.** The proposed amount and payment schedule must be disclosed in the initial IRB application. Additionally, the method of proposed payments to research subjects including *stipends* and *research incentives* must be disclosed in the IRB application.

9. **All communications relating to payments to research subjects (e.g., informed consent forms, advertisements, information sheets, etc.) must be reviewed and approved by the IRB before they are published.**
10. IRB-approved payments to research subjects must be clearly described in the informed consent form. The informed consent form must include the amount and schedule of payment to subjects, and should include the method of payment if notable (e.g., provision of gift certificates, recruitment incentives in lieu of cash payment). If applicable, the informed consent form should also describe conditions where no/partial payment will be provided to subjects (e.g., subject withdrawal).
11. Communications relating to payments to research subjects may not emphasize the payment (e.g., large or bold text).
12. The IRB has final authority with respect to the description of payments to research subjects in all research-related communications.

## **PROCESSING PAYMENTS TO RESEARCH SUBJECTS**

13. A Subject Stipend Invoice, which must be signed by the subject at the time the study visit occurs, provides the documentation and verification necessary to request dispersal of funds which have been provided for compensating the subject within the approved study budget. Subject Stipend Invoices should be submitted no later than five (5) working days after the corresponding study visit. Subject Stipend Invoices are considered confidential and will be held on file at the SRC to protect subject confidentiality. A new Subject Stipend Invoice for each visit must accompany each request for reimbursement.
14. Subject Stipend Invoices should be submitted for payment using an Accounts Payable Check Request Form (APR) as delineated in the Clinical Research Policy/Procedure: INVOICE PAYMENTS AND ACCOUNTS PAYABLE CHECK REQUESTS.
  - Only one visit may be recorded on the APR. Multiple visits cannot be combined on the same APR.
  - Unless the research subject will be receiving less than \$600 in the calendar year from Swedish, IRS regulations require the Social Security Number to be included on the form in the "Vendor Tax ID:" box.
15. A Vendor Check Request, which combines the subject's (Vendor) visit number, date, and signature on the same form as the Check Request, may also be used. In this alternative, the subject's informed consent form serves as the Agreement on File which is referenced, and no Subject Stipend Invoice is necessary. Please note that new rules only allow for one visit on a Vendor Check Request at a time. Multiple visits cannot be combined on the same Vendor Check Request. As with the APR, unless the research subject will be receiving less than \$600 in the calendar year from Swedish, IRS regulations require the Social Security Number to be included on the form in the "Vendor Tax ID:" box.
  - Only one visit may be recorded on the Vendor Check Request. Multiple visits cannot be combined on the same Vendor Check Request.

- Unless the research subject will be receiving less than \$600 in the calendar year from Swedish, IRS regulations require the Social Security Number to be included on the form in the “Vendor Tax ID:” box.
  - A Vendor Check Request may also be used to submit a request for reimbursement of a subject’s out-of-pocket expense. In order to process this payment, submit with the Vendor Check Request (1) documentation of sponsor’s agreement to reimburse the expense, and (2) appropriate documentation of the expense (e.g., receipt).
- 16.** Upon prior approval of the SRC Director, IRB-approved payments to research subjects may be tendered in cash in lieu of check payment. Cash payment may be appropriate when payment by check would cause inconvenience to a subject or when cash payment would mitigate subject privacy concerns.
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## Forms

- ◆ Subject Stipend Invoice
- ◆ Accounts Payable Check Request
- ◆ Vendor Check Request

## Supplemental Information

- Clinical Research Policy/Procedure: INVOICE PAYMENTS AND ACCOUNTS PAYABLE CHECK REQUESTS
- Clinical Research Policy/Procedure: RECRUITMENT/ADVERTISEMENT MATERIALS

## Expert Consultants

Manager – Institutional Review Office  
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## Regulatory Requirement

21 CFR 50.20  
45 CFR 46.116

## References

FDA Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators, “Payment to Research Subjects” (1998).

Office for Human Research Protections, IRB Guidebook, “Incentives for Participation” (1993).

## Addenda

1. Subject Stipend Invoice
2. Accounts Payable Check Request
3. Vendor Check Request

pk:Payments to Research Subjects – v. 2.0.doc (12/05/07)

<b>PAYMENTS TO RESEARCH SUBJECTS</b>
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**ADDENDUM 1**

**Subject Stipend Invoice**



## Subject Stipend Invoice

Protocol Name: \_\_\_\_\_ Protocol Number: \_\_\_\_\_

Visit Date: \_\_\_\_\_ Week/Visit #: \_\_\_\_\_

Project ID: \_\_\_\_\_ Stipend Amount: \_\_\_\_\_

Subject SSN: \_\_\_\_\_ OR  Amount less than \$600.00 per year

Check should be sent to the following address:

Name: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Subject Signature: \_\_\_\_\_

Study Personnel Signature: \_\_\_\_\_

<b>PAYMENTS TO RESEARCH SUBJECTS</b>
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**ADDENDUM 2**

**Accounts Payable Check Request**



SRC # (Admin Use Only):

**SWEDISH HEALTH SERVICES  
ACCOUNTS PAYABLE CHECK REQUEST  
(Non Standard Requisition)**

**NO ACCOUNTS PAYABLE CHECKS WILL BE PROCESSED WITHOUT A PURCHASE ORDER OR FULLY COMPLETED NON-STANDARD REQUISITION FORM. DOCUMENTATION, FOR INSTANCE, A VENDOR INVOICE MUST BE ATTACHED TO THIS FORM. INCOMPLETE REQUISITIONS WILL BE RETURNED TO THE ORIGINATING DEPARTMENT. PLEASE SEE INSTRUCTIONS**

Date Prepared:	<input type="text"/>	Invoice #	<input type="text"/>
Vendor Name and Address	<input type="text"/>	Invoice Date	<input type="text"/>
		SHS vendor code:	<input type="text"/>
		Vendor Tax I.D.:	<input type="text"/>

	ACCOUNT	DEPARTMENT	PROJECT	AMOUNT
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				

**TOTAL PAYMENT AMOUNT**    \$    -

**Purpose of Expenditure:**

PREPARED BY:	<input type="text"/>	<input type="text"/>
	(Print Name)	Phone

APPROVED BY:	<input type="text"/>	<input type="text"/>	<input type="text"/>
(Signature)		Date	Phone

**SUBMIT THE COMPLETED ACCOUNTS PAYABLE CHECK REQUEST WITH SUPPORTING DOCUMENTS TO RESEARCH ADMINISTRATION. RESEARCH ADMINISTRATION WILL SUBMIT APPROVED FORM TO ACCOUNTS PAYABLE.**



**SWEDISH MEDICAL CENTER**

**PAYMENTS TO RESEARCH SUBJECTS**

**ADDENDUM 3**

**Vendor Check Request**

SRC # (Admin Use Only):



SWEDISH HEALTH SERVICES

**VENDOR CHECK REQUEST**  
( to: Accounts Payable )

**NO ACCOUNTS PAYABLE CHECKS WILL BE PROCESSED WITHOUT A PURCHASE ORDER OR FULLY COMPLETED NON-STANDARD REQUISITION FORM. DOCUMENTATION (FOR INSTANCE, A VENDOR SIGNATURE) MUST BE INCLUDED ON THIS FORM. INCOMPLETE REQUISITIONS WILL BE RETURNED TO THE ORIGINATING DEPARTMENT. PLEASE SEE INSTRUCTIONS ON REVERSE SIDE OF FORM.**

Date Prepared:

**VENDOR TO BE PAID:**  
Payment Address

SHS vendor code:   
(See Instructions)

Vendor Tax I.D.:   
(See Instructions)

	ACCOUNT	DEPARTMENT	PROJECT	VISIT DATE	VISIT #	AMOUNT
1	770850					
2	770850					
7	770850					
11						
TOTAL PAYMENT AMOUNT						\$ -

Purpose of Expenditure:

Payment pursuant to Agreement on File. Signature of Vendor Below serves as Invoice.

Vendor Signature    
(Date)

Coordinator Name: (Printed Name: \_\_\_\_\_)   
Coordinator Signature:    
(Phone)

APPROVED BY: (Signature)     
Date (Phone)

**SUBMIT THE COMPLETED VENDOR CHECK REQUEST WITH SUPPORTING SIGNATURES TO THE ACCOUNTS PAYABLE DEPARTMENT.**