

LOUIS STOKES CLEVELAND VA MEDICAL CENTER
Medical Research Service
Standard Operating **Policy** and Procedure (SOP)

Effective Date: July 1, 2006

SOP Title: Paying Human Subject Volunteers with VA Appropriated Funds

SOP Number: HSP – 008A

SOP Version: .00

1. **PURPOSE:** To establish a procedure for payment to research subjects
2. **POLICY:** Payment of subjects must be a part of the Institutional Review Board (IRB) approved protocol and included in the IRB-approved informed consent form.
3. **DEFINITIONS:**
 - a. Form **1358** – Subject payment log
 - b. Form **10-7078** – "Authorization and Invoice for Medical and Hospital Services" is to be used to generate actual payment
4. **RESPONSIBILITIES:** List responsibilities of individuals
 - a. The Principal Investigator (PI) will assure that IRB approval has been granted prior to initiating subject participation payments.
 - b. The PI or designee will maintain a record of subject payments and assure adequate money is allotted to cover these payments.
 - c. The Administrative Officer (AO) or designee will set up payment accounts with Fiscal Service and approve all Form 7078's prior to submission to Fiscal Service.
5. **PROCEDURE:**
 - a. The amount, method and frequency of human subject volunteer payments are authorized by the IRB.
 - b. PI or designee will work with the AO to set up estimated quarterly expenditure.
 - c. The AO will initiate the official obligation by submitting an electronic 1358 to Fiscal Service. It is important to be aware of the VA fiscal year.
 - (1) The VA fiscal year is October 1 through September 30.
 - (2) The fiscal year is divided into four quarters
 - (a) October 1 – December 30
 - (b) January 1 – March 31
 - (c) April 1 – June 30

(d) July 1 – September 30

d. Fiscal Service will assign the Obligation Number.

(1) If it is likely that there will be numerous payments (i.e. 20 subjects) in one quarter, then a new obligation should be set up at the beginning of each quarter.

(2) VA accounting practices dictate that the balance in an obligation should be de-obligated after six months and a new obligation generated. Therefore, if it is likely that there will be only a few (20-30) payments throughout the fiscal year, an obligation will be set up for a period of six months or until the end of the fiscal year (whichever is less).

(3) The obligation number i.e. D66---, expires at the end of the fiscal year and cannot be used after September 30. A new 1358 must be generated through Fiscal Service and will have a new designation, i.e. D76---. This is done by the AO after communication from the study PI or designee.

e. Once an obligation number is assigned the AO will generate VA Form 4-1358 (See Appendix A). This form will be kept by the study PI or designee and used as the subject payment log. The study PI or designee must advise the AO when the obligation needs to be increased and by how much.

f. Once the obligation number has been assigned, actual payments can be made by generating VA Form 10-7078. (see Appendix B). The Study PI or designee generates this form.

(1) The AO or designee must sign the form in two places using a pen with blue or purple ink.

(2) The subject can be paid in one of two ways - either by receiving cash or requesting payment by check.

(a) CASH: To receive cash, the subject must take the original signed 10-7078 form and a picture ID to the Agent Cashier. The cash limit is \$500.

(b) CHECK: To receive a check, the statement "Please Pay by Check" must be placed in the body of the 10-7078 form (Box 6). The AO will sign the form and forward it to Fiscal Service for payment, which may take two weeks.

(c) A copy of the form should be given to the subject.

(d) If Volunteer subject payments exceed \$600 per year, they are considered taxable income. Fiscal Service provides a list of payees and payments to the IRS.

6. **REFERENCE:** VHA Handbook 1200.5

7. **RESCISSION:** July 1, 2009

8. **FOLLOW UP RESPONSIBILITY:** Research Compliance Officer

| | |
|--|---|
| Purpose <i>VOLUNTEER PAYMENTS</i> Investigator's Name XXX [inv proj #] (INV Initials) | <b style="font-size: 24pt;">1358 PO # - Obligation No. D66XXX |
|--|---|

| Date | Initials | Change Number | @ | Estimated Obligation | | | | | |
|----------|----------|--------------------------------------|---|----------------------|----|----------|--|---------|----|
| | | | | Increase | | Decrease | | Balance | |
| 01/03/06 | | FY-Qtr-XXXX-XXXX (assigned by VISTA) | | 300 | 00 | | | 300 | 00 |
| | | i.e. - 06-2-2521-0200 | | | | | | | |
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| Date | Reference # | Description | Authorization & Order Record | | | | Liquidation | |
|----------|-------------|-------------|------------------------------|----|------------|----|----------------------|----|
| | | | Individual or Daily | | Cumulative | | Unliquidated balance | |
| XX/XX/XX | .01 | Last name | 25 | 00 | 25 | 00 | 275 | 00 |
| | .02 | Last name | 40 | 00 | 65 | 00 | 235 | 00 |
| | .03 | | | | | | | |
| | .04 | | | | | | | |
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AUTHORIZATION AND INVOICE FOR MEDICAL AND HOSPITAL SERVICES

NOTICE: Public reporting burden for this collection of information is estimated to average 2 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to VA Clearance Officer (723), 810 Vermont Avenue NW, Washington DC 20120, and to the Office of Information and Regulatory Affairs, Project Officer (2900-0080), Office of Management and Budget, Washington DC 20503.. DO NOT send applications to this address.

| | | | |
|----------------------------|--|--|--|
| 1A. DATE OF ISSUE Today | 1B. ISSUING OFFICE VA Medical Center 10701 East Boulevard Cleveland, OH 44106 | 1C. DATE OF ISSUE (Month,day, year) Today | 1D. VETERAN'S NAME (First, middle initial, last) |
|----------------------------|--|--|--|

| | | |
|--|---|--|
| 2. NAME OF PHYSICIAN OR FACILITY Full Name Street Address City, State Zip | 3. VETERAN'S CLAIM NUMBER C - | 4. SOCIAL SECURITY NUMBER Subject's XXX-XX-XXXX |
| | 5. AUTHORIZATION VALID good for fiscal year | |
| | FROM 10/01/05 | TO 09/30/06 |

| | |
|--|-----------------------------|
| 6. SERVICES SHOWN BELOW ARE AUTHORIZED FOR THE PERIOD INDICATED IN ITEM 5 ABOVE. (See special provisions on the back of this form) Volunteer subject payment for whatever – blood draw, pulmonary test, questionnaire, etc PLEASE PAY BY CHECK (if applicable) | 7. FEE ###.## |
|--|-----------------------------|

| | | | |
|--|----------------------------------|-----|--------------------------------|
| 8. FEE SCHEDULE OR CONTRACT D66XXX. 01 then sequential .02, .03 | 9. AUTHORITY Title 38 USC 213 | 9A. | 10. ESTIMATED AMOUNT ###.## |
|--|----------------------------------|-----|--------------------------------|

| | |
|--|--|
| 11. FISCAL SYMBOLS 366/70161.001 (This changes at the beginning of a fiscal year) | 12. AUTHORIZED BY (Name and Title) JACLYN B. BLUME, Administrative Officer/Research |
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PART II - INVOICE

| 13. DATE(S) OF SERVICE | | | 14. DESCRIPTION OF SERVICE (If services furnished are identical to those authorized, enter the remark "As Authorized Above" in this column. Otherwise, itemize services.) | 15. FEE CLAIMED |
|------------------------|-----|------|---|-----------------|
| MONTH | DAY | YEAR | | AMOUNT |
| XX | XX | XX | As Authorized Above | \$ ###.## |

| | | | | |
|---|--|------------------|-------------------|-----------|
| 15A. SOCIAL SECURITY NUMBER OR EMPLOYER ID NUMBER | Individual or organization furnishing service, enter billing date and amount claimed. (Continue billing on back if necessary.) | 16. BILLING DATE | 17. TOTAL CLAIMED | \$ ###.## |
|---|--|------------------|-------------------|-----------|

PART III - FOR VA USE ONLY

| | | | |
|---|-------------|------|-----------------|
| ADMINISTRATIVE CERTIFICATION Payment of this will not cause payee to exceed maximum amount allowed. Services have been furnished as authorized or medically approved except as stated below. | AUDIT BLOCK | | |
| | AMOUNT DUE | DATE | VOUCHER AUDITOR |
| | \$ | | |
| REMARKS | | | |
| SIGNATURE AND TITLE JACLYN B. BLUME, Administrative Officer/Research | | DATE | |

PART IV - ACCOUNTING BLOCK

| | | | | | | | |
|------------|---------|-----|-----|-----|--------|----|---------------|
| ION PAT NO | TC & SC | CPF | LIQ | AMI | 1ST SA | \$ | DATE/INITIALS |
| | | | | | 2ND SA | \$ | |