

LOUIS STOKES CLEVELAND VA MEDICAL CENTER
Medical Research Service
SOP Cover Page

Effective Date: August 1, 2007

SOP Title: CPRS Medical Records for Non-Veteran Research Subjects and Veterans not
Currently Enrolled in the VA system

SOP Number: HSP-004

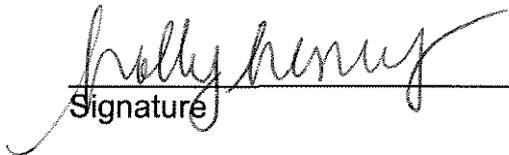
SOP Version: .01

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Signature _____ Date 8/2/07

Approved By:

Associate Chief of Staff for Research


Signature _____ Date 8/2/2007

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

Effective Date: August 1,2007

SOP Title: CPRS Medical Records for Non-Veteran Research Subjects and Veterans not Currently Enrolled in the VA system.

SOP Number: HSP - 004

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1. **PURPOSE.** This policy will outline the procedure for initiating Computerized Patient Record System (CPRS) Medical Records for non-veterans and Veterans not currently enrolled in the VA system.

2. **POLICY.** Non-Veterans (or Veterans not currently a part of the VA system) enrolled in a VA approved research study must have a medical record in the VA CPRS.

3. **DEFINITIONS.** None

4. **RESPONSIBILITIES.** The Principal Investigator (PI) must insure that non-veteran patients enrolled in VA approved studies are entered into the VA CPRS.

5. **PROCEDURE**

a. When a **Veteran not currently in the VA system** is enrolled in a research study, the veteran should be entered into the VA system through the eligibility department (x5572, room 1B-119). The veteran needs to take a copy of their DD-214 to eligibility.

b. When a **non-Veteran is enrolled** in a research study the following information regarding the individual must be forwarded through VISTA to the mailgroup **G.Research Participant.**

(1) Name

(2) Home Address

(3) Date of Birth

(4) Full Social Security Number

(5) Phone Number

(6) Work Phone Number (optional)

(7) Next of Kin (optional)

(8) Veteran Status, if the individual is a Veteran you need to include if they have their own personal health insurance

(9) Emergency Contact

(10) Remarks: i.e. Alerts

c. If you do not have access to VISTA, supply the same information in hard copy to Holly Henry in the Medical Research Service Office.

d. Follow SOP HSP- 003 "Documentation in Patient's Medical Record of Enrollment Contact, Actual Enrollment and End of Study Participation" for documenting consent, enrollment and completion of study in the subject's medical record.

e. Exceptions to this procedure are outlined in Medical Research Service SOP HSP-017 "Exception to the Requirement for CPRS Documentation."

6. **REFERENCE:** VHA Handbook 1200.5, Human Research Protection Program Standard Operating Procedures; Medical Research Service SOP HSP-017 "Exception to the Requirement for CPRS Documentation."

7. **RESCISSION:** Medical Research Service SOP HSP-004 was rescinded. The review date for this SOP is August 1, 2010.

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