

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

Effective Date: August 1, 2007

SOP Title: Documentation in Patient's Medical Record of Enrollment Contact, Actual Enrollment and End of Study Participation

SOP Number: HSP-003

SOP Version: .01

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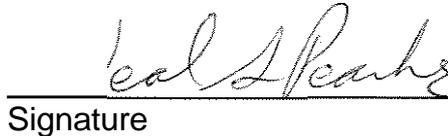

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Date

Approved By:

Associate Chief of Staff for Research


Signature

8/2/2007

Date

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

Effective Date: August 1,2007

SOP Title: Documentation in Patient's Medical Record of Enrollment Contact, Actual Enrollment and End of Study Participation.

SOP Number: Human Researchers - HSP-003

SOP Version: .01

1. **PURPOSE.** This policy will outline subject enrollment and subject study completion documentation requirements in the patient medical record.

2. **POLICY**

a. It is VHA policy that a progress note documenting the informed consent process (whether written or oral) be entered into the medical record.

b. An entry must also be placed in the medical record when the human subject (VA or non-VA) is actually entered into the study and when the human subject's participation is terminated.

c. Consent and entry notes can be combined when both occur at the same visit.

d. It is suggested that a progress note must be entered into the medical record when a VA patient is contacted to participate in a research study and the patient declines participation.

3. **DEFINITIONS.** None

4. **RESPONSIBILITIES.** The Principal Investigator (PI) must insure that documentation of enrollment contact, the informed consent process, entry into the study, and termination of participation in the study is entered into the human subject's medical record in the Computerized Patient Record System (CPRS).

5. **PROCEDURE**

a. If the IRB has determined that the study requires special 'flagging' of the medical record, follow the medical research service policy, HSP - 005 "Flagging of Medical Research Subjects." That policy outlines the process for research flagging. Study contact without enrollment and completion of study for research subjects still follow this procedure.

b. In CPRS there is a progress note template entitled, "**Research Study Note**". This can be used when:

- (1) A patient is contacted to participate in a research study but declines to participate.
- (2) A patient is consented to participate in a research study.
- (3) A patient is actually entered into a research study.
- (4) A patient's participation in a study has ended.

c. When enrollment and consent (whether oral or written) occur at the same time, one note can be entered.

d. If you make your own progress note rather than using the CPRS template when documenting the informed consent process you must include:

- (1) The name of the study.
- (2) The person obtaining the subject's consent.
- (3) A statement that the subject or the subject's legally-authorized representative was capable of understanding the consent process.
- (4) A statement that the subject was given the opportunity to ask questions.

e. If you make your own progress note rather than using the CPRS template when documenting end of study participation, you must include:

- (1) The name of the study.
- (2) The date participation was ended.
- (3) The reason for ending study participation. The note must include a detailed explanation if participation has ended because of anything but completion of the study and/or completion of the enrollment period.

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

If you need assistance with CPRS please contact Holly Henry in the research office, x4657.

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 Standard Operating Procedure HSP-003.00 dated September 1, 2004 was rescinded. Review date for this policy is August 1, 2010.

8. FOLLOW UP RESPONSIBILITY: Research Service, Clinical Coordinator

9. ATTACHEMENTS: CPRS HELP

CPRS HELP

1. After selecting the patient in CPRS
2. select the **Notes** tab
3. select **New Note**
4. select the scheduled clinic appointment or **New Visit**
5. if you choose New Visit select your specific **Research Clinic** OR the generic W **RESEARCH/A**
6. for the **Progress Note Title** choose **RESEARCH STUDY NOTE (T)**
7. Use the template to document the consent process and enrollment information
8. After completing the template portion of the note, click OK, you can then enter any additional information directly into the note.
9. Upon exiting CPRS you will be prompted to sign (electronically) your note
10. You will be prompted to select the **Primary Provider**, depending on your specific study this will be the **Principal Investigator** or the **Responsible Investigator**.