

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

**Effective Date:** August 3, 2007

**SOP Title:** Exception to the Requirement for CPRS Documentation  
**SOP Number:** HSP-017  
**SOP Version:** .00

**Author:**

**Name:** Betty Dunger  
**Title:** Research Compliance Officer  
**Department:** Research

  
Signature \_\_\_\_\_ Date 8/3/07

**Approved By:**

Associate Chief of Staff for Research

  
Signature \_\_\_\_\_ Date 8/6/07

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

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1. PURPOSE. This policy outlines the procedure for requesting an exception to the requirement for documentation in the Computerized Patient Record System (CPRS) for research participants.

2. POLICY: There may be circumstances when documentation of participant enrollment and study completion in CPRS is not required. For example:

- a. The study is determined to be of minimal risk
- b. The study involves only a single visit and/or is of short duration (less than one hour)
- d. It is important to protect participant privacy
- e. It is necessary to maintain study blinding
- f. The study only involves screening procedures, for non-veterans

A Principal investigator (PI) may request an exception to the requirement for CPRS documentation in CPRS.

3. DEFINITIONS. None

4. RESPONSIBILITIES:

a. The PI must ensure that the enrollment contact, the informed consent process, entry into the study and termination of participation in the study is documented for all participants enrolled in VA approved studies, whether or not an exception to the requirement for CPRS documentation has been granted.

b. The Research Compliance Officer (RCO) will determine, on a case-by-case basis whether or not an exception to the requirement for CPRS documentation will be granted.

5. PROCEDURES

a. The PI must submit a written request for an exception to the requirement for CPRS documentation to the RCO. The request must include the following:

- 1) IRB number, if assigned
- 2) Study title
- 3) Risk determination of the study
- 4) Justification for the request
- 5) Where research participant documentation, including data security precautions, will be

maintained.

b. The RCO will review all requests, make a determination and prepare a response for all exception requests indicating approval or denial. A copy will be forwarded to the PI and the IRB office.

c. The RCO will maintain a record of all waivers in the R&D study file.

**6. REFERENCE:** VHA Handbook 1200.5, HSP-003 "Documentation in Patient's Medical Record of Enrollment Contact, Actual Enrollment and End of Study Participation" and HSP-004 "CPRS Medical Records for Non-Veteran Research Subjects and Veterans not Currently Enrolled in the VA System".

**7. RESCISSION:** The review date for this SOP is August 3, 2010

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