

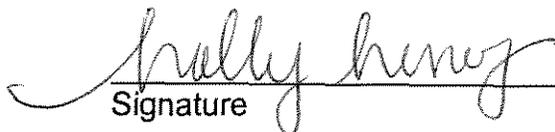
LOUIS STOKES CLEVELAND VA MEDICAL CENTER  
Medical Research Service  
SOP Cover Page

**Effective Date:** August 1, 2007

**SOP Title:** Medical Research Service Standard Operating Policy/Procedure (SOP)  
**SOP Number:** SD-001  
**Version:** .01

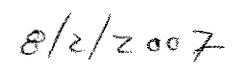
**Author:**

**Name:** Holly Henry  
**Title:** Program Analyst  
**Department:** Research Service

 \_\_\_\_\_  \_\_\_\_\_  
Signature Date

**Approved By:**

Associate Chief of Staff for Research

 \_\_\_\_\_  \_\_\_\_\_  
Signature Date

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

**Effective Date:** August 1, 2007

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1 **PURPOSE.** To establish formal guidelines for submitting, classifying and approving Medical Research Service Standard Operating Policies and Procedures (SOPs).

2 **POLICY.** This policy applies to all SOPs developed within the Medical Research Service.

3. **DEFINITIONS.** None

4. **RESPONSIBILITIES**

a. The Research Compliance Officer (RCO) will receive and pre-review all SOPs prior to submission to the SOP Committee.

b. The SOP Committee will meet formally and review SOPs for content and format.

c. The Associate Chief of Staff for Research and Development (ACOSIR) will have final approval authority for SOPs.

5. **PROCEDURES**

a. SOPs will be submitted electronically through the RCO to the SOP Committee.

b. SOPs recommended for approval by the SOP Committee will be forwarded to the ACOSIR for final approval and signature.

c. Animal Researcher – Animal Research Facility (ARF) and Institutional Animal Care and Use Committee (IACUC) SOPs will be reviewed and approved by the IACUC prior to submission to the SOP Committee and final approval by the ACOSIR.

d. Human Researcher – Institutional Review Board (IRB) SOPs will be reviewed and approved by the IRB prior to submission to the SOP Committee and final approval by the ACOSIR.

e. Safety – Subcommittee on Research Safety (SRS) SOPs will be reviewed and approved by the SRS prior to submission to the SOP Committee and final approval by the ACOSIR.

## f. SOP Numbering

1) SOPs will be identified by Functional Group and numbered sequentially

- a) Administrative: ADM-00x
- b) All Research Personnel: SD-00x
- c) Animal Researchers: ARF-00x
- d) Basic Science Researchers: BS-00x
- e) Human Researchers: HSP-00x
- f) Information Systems: IS-00x
- g) Institutional Review Board: IRB-00x
- h) Miscellaneous: MS-00x
- i) Subcommittee on Research Safety: SRS-00x
- j) Research & Development Committee: RD-00x

2) SOPs will also include a Version Number. The first version of the SOP will be 00.

g. The SOP Committee designee will forward approved SOPs to IRM for posting on the Medical Research Service Intra and Internet Site.

1) If the nature of the SOP, such as Animal Researchers ARF is 'controversial,' the SOP will be password protected. The SOP Committee will make this determination.

h. The standard approval period for SOPs will be three years.

i. As policy and procedure change, SOPs may be rescinded, retired and/or revised through the SOP Committee.

j. All SOPs will follow the same format of this SOP. The outline template and instructions can be obtained electronically from the RCO and the Medical Research Service Intranet and Internet site.

**6. REFERENCE:** Medical Center Policy 002-005 Electronic Medical Record Policies. Appendix A: Medical Research Service SOP Template.

**7. RESCISSION:** Medical Research Service SOP SD-001.00 dated September 1, 2004 was rescinded. The review date for this SOP is August 1, 2010.

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

## **APPENDIX A - Medical Research Service SOP Template**

Some helpful hints for using the SOP template.

- 1) A Hard Return (enter) at the end of a line will keep you at the same level in the outline but take you to the next number or letter.
- 2) A Hard Return (enter), Followed by a Tab will take you to the next level of the outline.
- 3) A Hard Return (enter), Followed by a Shift/Tab will take you back to the previous level.
- 4) Font should be 11pt Times New Roman

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

**Effective Date:** Will be completed when the policy is approved

**SOP Title:** Insert the SOP Title

**SOP Number:** If this is a new SOP, the number will be assigned by the SOP Committee. If this is a review of an existing policy, include the SOP Number

**SOP Version:** Begin with .00

**I . PURPOSE:** Broad Statement of Purpose

2. **POLICY:** Broad Statement of the Policy

3. **DEFINITIONS:** List any non-common definitions

4. **RESPONSIBILITIES:** List responsibilities of individuals

a. Example of format

1) Example

a) Example

i. Example

ii. Example

aa Example

2) Example

b. Example

5. **PROCEDURES:** Outline SOP Procedures

6. **REFERENCE:** Site Medical Center Policy, Documents, VA Directives etc. that pertain to this SOP

7. **RESCISSION:** Policy XXX-XXX dated (date of previous version of policy) has been rescinded. The review date of this policy is (three years from today's date). This will be completed by the SOP Committee

8. **FOLLOW UP RESPONSIBILITY:** This is generally the author of the policy