

VAMHCS RESEARCH SERVICE  
STANDARD OPERATING PROCEDURE

SOP #HRP 07.02G

Approval Date: 7/13/06

## WRITING STANDARD OPERATING PROCEDURES

### OBJECTIVE:

- To provide a consistent format for writing standard operating procedures (SOPs).
- To assist the Research Service and investigators in complying with Good Clinical Practice and FDA regulations (21 CFR 50, 56, 312, 314), UMB IRB policies, VA policies and BREF policies.
- To assure that Research Service SOPs (and the policies and procedures that they describe) receive proper review and approval.
- To assure that VAMHCS research staff are informed of current SOPs and have a reference for Research Service policies and procedures.

### SCOPE:

This SOP describes the Research Service method of writing, reviewing, approving, and revising its standard operating procedures.

***However, investigators may use this SOP as a method for developing their own standard operating procedures.***

### RESPONSIBILITIES:

- The Research Service Office of Research Compliance is responsible for preparing SOPs according to the format outlined here.
- VAMHCS research staff (investigators, coordinators, research assistants, etc.) is responsible for complying with SOPs and awareness of new or revised SOPs.

### DOCUMENTS (ATTACHMENTS):

Content Codes for SOP Numbering	(Appendix A)
Template of standard operating procedure format	(Appendix B)

### SEE ALSO

Research Service Standard      “Study-Specific SOPs (SSSOPs)”

### PROCEDURE:

Writing SOPs (HRP 07.05G)  
Replaces version 1.0

Version 2.0

Review due: 7/09

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1. Writing the SOP:

- 1.1 The writer decides on the level of detail for the SOP by determining whether staff should have flexibility when performing the activity (a less detailed SOP would therefore be best) or whether precise steps for regulatory purposes are necessary (a more detailed SOP would be best).
- 1.2 The writer prepares a step-by-step list of activities, including who will perform the activity. The SOP should be written in the format described in Section 2.0 below.
- 1.3 If necessary, tools (such as forms, templates, checklists, etc.) are designed. These tools are used for implementation of the SOP.
- 1.4 The first draft of the SOP is completed and submitted to appropriate staff and management, including the R&D Committee, for review and assessment of accuracy. Each activity is evaluated for efficiency, effectiveness, and compliance with FDA, VA and IRB regulations and guidelines.
- 1.5 After the procedure is tested, all comments and revisions are evaluated and are included in the final version as appropriate.
- 1.6 The final version is sent to the R&D Committee for approval.
- 1.7 The final version signed and dated by the Chairperson of the R&D Committee and the ACOS/R&D.
- 1.8 Copies of the final version are distributed throughout the organization.

2.0 Format:

2.1 Header:

*Upper right corner:* shortened, topic title of SOP followed by hyphen and "[page number] of [number of pages]"

*Center:* "VAMHCS RESEARCH SERVICE / STANDARD OPERATING PROCEDURE"

2.2 Footer:

*Left side:* file name of SOP, "Replaces version [\_\_\_]"

*Center:* version number (see #3.0 below)

*Right side:* "Review Due" (1 year from Approval Date)

2.3 Text, upper left corner of page 1:

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SOP#: (See #3.0 below)

Approval date: date when SOP takes effect

- 2.4 Title of SOP:  
The wording should be descriptive but not too long.
- 2.5 Objective of SOP:  
The writer describes the purpose of the SOP: what it is supposed to accomplish, why it is necessary, etc.
- 2.6 Background and/or Scope:  
The writer uses a paragraph or two to place the SOP in historical or regulatory context. A “Background” section is not necessary for all SOPs. It is necessary for SOPs in which knowledge of its context is important. For example, the Standard on “Study-Specific SOPs” contains a Background section explaining the difference between SSSOPs and general SOPs.  
Occasionally, both “Background” and “Scope” sections are appropriate.
- 2.7 Responsibilities:  
The writer lists the people/offices responsible for the oversight of the SOP and for performing the activities.
- 2.8 Definitions:  
An easy reference in which selected words or phrases are listed with their definitions. The defined word/phrase should be in bold, followed by a fairly detailed explanation of the word/phrase. This section is not necessary for all SOPs but is especially helpful for SOPs that contain regulatory or other terminology with precise meanings. The defined word should also be in bold when it is first mentioned in the text of the SOP. Definitions should also be placed in the SOP Glossary.
- 2.9 Documents / Attachments:  
The writer enumerates the attachments/appendixes by letter or number and the titles of the attachments. Attachments may include forms, checklists, templates, addenda, or other applicable materials.
- 2.10 See Also:  
The writer describes or lists what regulations, guidelines or policies of specific committees or agencies the SOP is meant to fulfill. It may also list other SOPs that are directly related to or affected by the SOP.

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- 2.11 Procedures:  
The writer describes the tasks or step-by-step procedures to complete the activities. The procedure also includes mechanisms for enforcement, documentation, etc. It includes definitions as necessary.
- 2.12 Compliance:  
The writer describes the procedure for monitoring compliance with the SOP and penalties for non-compliance if applicable. This section is not necessary for all SOPs (such as instructional, “how-to” SOPs). It *is* necessary for SOPs that fulfill a regulatory or institutional policy need.
- 2.13 References:  
The writer lists sources used (if any) to write or develop the SOP. Typically this includes federal or institutional regulations and policies, as well as other sources.
- 2.14 Approval:  
This is usually a standard sentence such as: “This SOP entitled “[Title]” has been approved [re-approved] by the [person charged with this duty], effective [date]. If appropriate to the setting, a signature line & date may be placed.
- 3.0 Numbering
- 3.1 SOP number:
- 3.1.1 The SOP number is in the “\_\_ . \_\_” format.
- 3.1.2 SOPs are grouped according to topic/type/content. Each group is assigned a number. This number is the first digit of the SOP number. For example, SOPs having to do with quality assurance activities are all in the QA (2.0) group and all begin with the digits 02: HRP 02.\_\_. See Appendix A for a list of the groups used by the VAMHCS Office of Research Compliance.
- 3.1.3 Within each group, SOPs assigned to that group are placed in a logical order and are numbered consecutively in the position following the decimal place: \_\_.01+.
- 3.1.4 All Office of Research Compliance SOP numbers are preceded by the initials “HRP” (for “Human Research Protection” SOP).
- 3.2 Version number:
- 3.2.1 Version number is in the “\_\_ . \_\_” format.

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- 3.2.2 The first digit changes whenever there are substantive changes to the SOP. The version changes to 2(+).0 with new approval/review dates. For example correction of a typographical error, or a change in page format would not generate a change in version number, but a change in a procedure would: "Version 1.0" becomes "Version 2.0", etc.
- 3.2.3 The second digit changes at yearly review if there are no changes to the SOP and it is renewed as-is (except for typographical errors, page format, etc). There is a memo-to-file stating that the SOP is renewed without change and the version number changes to \_\_.1(+) with new approval/renewal dates.
- 4.0 Implementation
- 4.1 After the SOP is approved by the R&D Committee, the Office of Research Compliance retains hard copies in the "SOP Binder" located in the Research Service Office (3A-125). If possible to place on a website for distribution, a PDF version of the SOP will be created.
- 4.2 The Office of Research Compliance notifies research staff of the new SOP via e-mail, staff meeting or other means.
- 4.3 The Research Service arranges for staff in-services if these are considered necessary for correct implementation of the SOP. These in-services may be conducted by e-mail, during a staff meeting, as a formal class or any other means appropriate to the material and to the staff affected. Lists of attendees are kept.
- 4.4 **Investigators:** If a specific sponsor or study requires that a particular task be performed in a way that differs from your established SOP, you may approve a deviation to your SOP. The new SOP is delineated for that study only and is filed in study binder as a SSSOP (see SOP# \_\_, "Study-Specific SOPs") along with a "memo to file". The "memo to file" states that the deviation applies only to the study in question, that the deviation is at the sponsor's request, and that it expires as soon as the study has completed.
- 5.0 SOP Revisions and Yearly Review
- 5.1 Each SOP is reviewed on a yearly basis for possible revision due to changes in regulations or institutional procedures. Revisions may occur more frequently especially with regard to federal, VA or IRB regulations.

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- 5.2 Revisions go through the same development process described in sections 1.0 and 2.0 above.
- 5.3 Each revision is labeled with a new version number (see section 3.2 above) with an effective date listed. The revision is approved and signed-off by the R&D Committee.
- 5.4 Staff is informed of the revision and inserviced on it as described in 3.2 and 3.3 above.
- 5.5 The Office of Research Compliance maintains a file of all old versions of SOPs. Monitoring entities should audit according to the SOP that was in effect at the time of the study.

## 5. APPROVAL

This SOP entitled "Standard Operating Procedure for Writing SOPs" has been re-approved by the Medical Center Director, effective 07/13/06.

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## Appendix A

### Content Code for SOP Numbering

- 01 Research Service – Administration
- 02 QA
- 03 Informed consent
- 04 Training & Education
- 05 Pharmacy
- 06 Devices & Procedures
- 07 Investigator Study Conduct

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## Appendix B

### Template of standard operating procedure (SOP) format

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[short name of SOP] - 9

[Name of Unit]  
STANDARD OPERATING PROCEDURE

SOP# \_\_\_\_  
Effective: [date]

[TITLE]

OBJECTIVE:

- 
- 

BACKGROUND

SCOPE

RESPONSIBILITIES:

- 
- 

DEFINITIONS

DOCUMENTS / ATTACHMENTS:

- (Appendix 1)
- (Appendix 2)
- (Appendix 3)

SEE ALSO:

PROCEDURES

1.
  - 1.1.
  - 1.2.
  - 1.3.

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2.

2.1.

2.2.

2.3.

COMPLIANCE

REFERENCES

APPROVAL

This SOP entitled "[\_\_\_\_\_]" has been approved effective [DATE].

\_\_\_\_\_  
(signature) (print) (date)

\_\_\_\_\_  
(signature) (print) (date)

[file name]

Replaces version(s): \_\_\_\_\_ [ DRAFT/Version # \_\_. \_\_ ]

Review due: \_\_\_\_\_