

VAMHCS RESEARCH SERVICE
STANDARD OPERATING PROCEDURE

SOP #HRP 07.05

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Author	Jessica Mendoza		
Changes	<ul style="list-style-type: none"> • Changed the general approval period to 3 years (from 1 year) • Changed the approval to come from ACOS/R (from the MCD) 	New Version #	3.0
Approved	Christopher T. Bever, ACOS/R&D Date: 1/31/2012		
File Name	\\ Writing SOPs (HRP07.05) 2012v3.0		

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 , , VA policies, UMB IRB 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 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)"

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PROCEDURE:

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 key stakeholders and appropriate staff for review. Each activity is evaluated for efficiency, effectiveness, and compliance with 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 ACOS/R&D for approval.
- 1.7 The R&D Committee is notified of the new/revised SOP.
- 1.8 Copies of the final version are distributed throughout the organization and uploaded into the [Research Service website](#).

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” (generally 3 years from Approval Date)
- 2.3 Text, upper left corner of page 1:
SOP#: (See #3.0 below)
- 2.4 “Version-Approval” box
- 2.5 Title of SOP:
The wording should be descriptive but not too long.
- 2.6 Objective of SOP:
The writer describes the purpose of the SOP: what it is supposed to accomplish, why it is necessary, etc.

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- 2.7 **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.
- 2.8 **Responsibilities:**
The writer lists the people/offices responsible for the oversight of the SOP and for performing the activities.
- 2.9 **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.
- 2.10 **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.
- 2.11 **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.
- 2.12 **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.
- 2.13 **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.
- 2.14 **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.
- 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

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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.

3.2.2 The first digit (in front of the decimal) changes in increments of "1" at the time of scheduled review. For example, "version 1.0" becomes "version 2.0" at the time of its renewal. .

3.2.3 The second digit (after the decimal point) changes in increments of ".1" when there are revisions during the period of approval. For example, "version 1.0" becomes versions "1.1", "1.2", etc. if revisions are made during its 3-year approval period

4.0 Implementation

4.1 After the SOP is approved by the ACOS/R&D, the R&D Committee is notified and the SOP is posted on the [Research Service website](#).

4.2 The Research Service notifies the research community through "Research Service Hot Topics" or "Bulletins", staff meetings 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 schedule appropriate for the SOP. For most SOPs, a triennial review is acceptable. Some SOPs may require more frequent review based on importance, frequency of changes in the regulatory environment, etc.

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 approval date listed in the "Version-Approval" box. The revision is approved and signed by the ACOS/R&D.

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- 5.4 Staff is informed of the revision and inserviced on it as described in 3.2 and 3.3 above.

- 5.5 The Research Service 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.

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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

SOP# ____

Version	[new version number]	Origin	[original version number]
Author	[name]		
Changes	•	New Version #	[number]
Approved	[name], ACOS/R&D Date:		
File Name	Ex: \ Writing SOPs (HRP07.05G) 2012v3.0		

[TITLE]

OBJECTIVE:

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-

BACKGROUND

SCOPE

RESPONSIBILITIES:

-
-

DEFINITIONS

DOCUMENTS / ATTACHMENTS:

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

SEE ALSO:

PROCEDURES

- 1.
- 1.1.

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1.2.

1.3.

2.

2.1.

2.2.

2.3.

COMPLIANCE

REFERENCES

[file name]

Replaces version(s): _____

[DRAFT/Version # __. __]

Review due: _____