Category:	Administrative	Page 1 of 2
Title:	Developing Standard Operating Procedures	SOP#: 10.01.3
Date First Effective: June 1, 2002	Revision Date: April 26, 2010	

OBJECTIVE

This standard operating procedure (SOP) describes the preparation of the written procedures that are followed to ensure compliance with federal, state, and institutional regulations and guidelines governing clinical trials activities. These procedures apply to all clinical trials activities conducted in the School of Medicine at the University of Virginia.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.60	General responsibilities of investigators
May 9, 1997	International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline
January 1988	Guidelines for the Monitoring of Clinical Investigations
	FDA Internal Compliance Program Guidance Manual 1994; 7348.811: Clinical Investigators

REFERENCES TO OTHER APPLICABLE SOPs

All SOPs are applicable to this SOP.

ATTACHMENTS

Standard Operating Procedures Approval and Distribution form

PROCEDURES

- Personnel writing and approving standard operating procedures.

1. Format all SOP headers to the following format:

    - **Category:** Reflect the general category to which the SOP pertains.
    - **Page ____ of ____:** Shows the specific page number as well as the total number of pages comprising the SOP.
    - **Title:** A general description of the subject of the SOP.
    - **SOP Number:** Identification number assigned before entering into the system of approved SOPs. The first field consists of two numbers and pertains to the category in which the SOP can be found. The second field is the SOP number and is assigned in numerical order. The third field represents the version number. Only the most recent version of each SOP will be posted on-line.

- **Date First Effective:** Represents the date on which the content of the SOP first became official.

- **Revision Date**: Reflects the date that this revision became effective. (Note: If the SOP has never been revised, this field will remain blank).

2. Write procedures in an outline form using the topics in the following order:

    - **Objective:** This states the intent and general description of the SOP.

    - **Applicable Regulation and Guidelines:** This topic describes any regulations or guidelines that can be used as a resource for this procedure.

    - **References to Other Applicable SOPs:** This topic will describe any other SOPs which may provide additional information on the subject described in the current SOP.

    - **Attachments:** This topic describes any attachments associated with this SOP. They will be labeled sequentially.

    - **Procedures:** This section provides step-by-step instructions for completing the tasks included in each SOP. The role(s) responsible for performing each step is listed in the left-hand column.

- Clinical Trials Office

3. Ensure revised SOP satisfies established format requirements. Edit as necessary.

4. Ensure revised SOP is compliant with federal, state and institutional regulations governing clinical trial activities.

5. Assign the SOP category and SOP#.

6. Complete "Standard Operating Procedures Approval and Distribution Form".

7. Update the table of contents of SOPs.