Category:	Administrative	Page 1 of 2
Title:	Revising Standard Operating Procedures	SOP#: 10.02.3
Date First Effective: June 1, 2002	Revision Date: April 26, 2010	

OBJECTIVE

This standard operating procedure (SOP) describes the steps involved in the revision of the procedures that will ensure compliance with federal, state, and institutional regulations and guidelines governing clinical trial activities. These procedures apply to all clinical trials 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

Attachment: Standard Operating Procedures Approval

PROCEDURES

- Clinical Research Personnel

1. Notify the Clinical Trials Office with the request to revise/add a standard operating procedure.
2. Provide the Clinical Trials Office with the rationale for the change.
3. Draft the new/revised standard operating procedure (and accompanying attachment(s), if applicable).
4. Submit the revisions to the School of Medicine Clinical Trials Office.

- Clinical Trials Office

5. Ensure revised SOP satisfies established format requirements. Edit as necessary.
6. Ensure revised SOP is compliant with federal, state and institutional regulations governing clinical trial activities.
7. Assign the SOP category and SOP#.
8. Complete "Clinical Trial Standard Operating Procedures Approval and Distribution Form".

9. Transfer the previous version to the "Archived SOP" file if action includes revising or retiring an existing SOP.

10. Update the table of contents of SOPs.