

Category:	Administrative	Page 1 of 1
Title:	Distributing New and Revised Standard Operating Procedures	SOP #: 10.03.3
Date First Effective:	June 1, 2002	Revision Date: April 26, 2010

OBJECTIVE

This standard operating procedure (SOP) describes the steps involved in the distribution of new and revised 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 Form](#)

PROCEDURES

- Clinical Trials Office
 1. Post an approved standard operating procedure (or approved revised SOP) on-line at <http://www.healthsystem.virginia.edu/internet/cto>
 2. Notify research staff of the addition/revision via an e-mail notice.
 3. File the new/revised SOP along with the "Clinical Trial Standard Operating Procedures Approval and Distribution Form" in the SOM Clinical Trials Office.
 4. Maintain an SOP table of contents by number and title of the SOPs.
 5. Maintain a table of contents of all attachments referenced in the clinical trials standard operating procedures.