

Category:	Administrative	Page 1 of 1
Title:	Quality Review of Standard Operating Procedures	SOP #: 10.04.2
Date First Effective:	June 1, 2002	Revision Date: August 30, 2004

OBJECTIVE

This standard operating procedure (SOP) describes the steps involved in conducting a quality review of the procedures that are followed to 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 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

None

PROCEDURES

- Clinical Trials Office
 1. Review current SOPs, as well as the applicable attachments, considering applicability to current practice, compliance with current regulations, and accuracy of the content. Review to take place annually.
 2. Refer to SOP # 10.02 "Revising Standard Operating Procedures" if any changes are to be made. Refer to SOP # 10.01 "Developing Standard Operating Procedures" if any new procedures are to be added.
 3. Retain all documentation of the annual SOP review.