Category:	Administrative	Page 1 of 1
Title:	Communication with Clinical Trial Sponsor or CRO	SOP #: 10.08.1
Date First Effective: June 1, 2002	Revision Date:	

OBJECTIVE

This standard operating procedure (SOP) applies to communications between research personnel and sponsor/CRO personnel regarding any aspect of a clinical trial being conducted under the direction of a University of Virginia School of Medicine Investigator.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
21 CFR 312.32	IND safety reports
21 CFR 312.33	Annual reports
21 CFR 312.44	Termination
FDA Information Sheets, October, 1995	Sponsor-Investigator-IRB Interrelationship
May 9, 1997	International Conference on Harmonisation; Good Clinical Practice: Consolidated Guidelines

REFERENCES TO OTHER APPLICABLE SOPs

SOP#: 10.06	Responsibilities of the Research Team
SOP#: 10.07	Management of Clinical Trial Regulatory Files
SOP#: 20.01	Assessment of Protocol Feasibility
SOP#: 20.05	Pre-Study Site Evaluation Visit
SOP#: 20.06	Site Initiation Meeting
SOP#: 30.03	Obtaining Informed Consent

ATTACHMENTS

Attachment: Telephone Contact Log

PROCEDURES

- Research Personnel

1. Communicate regularly and appropriately with sponsor/CRO about study-related issues.
2. Document important conversations.

- Clinical Research Coordinator

3. Retain originals or photocopies of all relevant communication (telephone contacts, facsimiles, including facsimile confirmations, e-mail correspondence, etc.) and file with regulatory documents. (File in source document if communication applies to a study subject).