OBJECTIVE

This standard operating procedure (SOP) described the activities involved in maintaining the regulatory files for all clinical studies conducted under the direction of a University of Virginia School of Medicine Investigator.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.68	Inspection of investigator's records and reports
FDA Information Sheets, October, 1995	Recordkeeping in Clinical Investigations
May 9, 1997	International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline

REFERENCES TO OTHER APPLICABLE SOPs

SOP#: 10.06	Responsibilities of the Research Team
SOP#: 20.05	Pre-Study Site Visit
SOP#: 20.06	Site Initiation Meeting
SOP#: 20.08	Study Start-up
SOP#: 30.09	Sponsor/CRO Monitoring Visit
SOP#: 40.01	Study Termination

ATTACHMENTS

Attachment: Regulatory Files Content

PROCEDURES

- Clinical Research Coordinator

1. For each study, create a series of file folders or start a binder for documents collected during the study (Refer to Attachment: Regulatory Files Content). Use sponsor format if applicable and if provided.

2. Maintain and update the file folders or binder as necessary, adding appropriate documents as they are generated or received.

3. If study is sponsored, identify with sponsor which documents they require to be sent to them. Determine which documents sent to the sponsor must be original and which can be copies.

4. Retain copies of all original and revised documents (e.g., protocol, investigator's brochure, informed consent form, IRB approval, correspondence).

5. Retain copies of all documents/submissions/correspondence sent during study (e.g. to IRB, to sponsor).

6. Ensure that subject records and regulatory files are kept confidential and are stored in a secure, limited-access location.

7. Prior to visits scheduled by monitors and auditors, review content of regulatory files and subject records for completeness.