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Title:	Responsibilities of the Research Team		SOP #: 10.06.3
Date First Effective:	June 1, 2002	Revision Date:	April 26, 2010

OBJECTIVE

This standard operating procedure (SOP) defines the responsibilities of the research team for conducting clinical studies at this investigative site. It identifies administrative accountability as well as general responsibilities of the research team and of individual team members for fulfilling regulatory and clinical requirements.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50	Protection of Human Subjects
21 CFR 54	Financial Disclosure by clinical investigators
21 CFR 312.53	Selecting investigators and monitors
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.61	Control of the investigational drug
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.64	Investigator reports
21 CFR 312.66	Assurance of IRB review
21 CFR 312.68	Inspection of investigator's records and reports
21 CFR 312.69	Handling of controlled substances
45 CFR 46	Protection of Human Subjects
January, 1988	Guidelines for the Monitoring of Clinical Investigations
FDA Information Sheets, October, 1995	Frequently Asked Questions, Continuing Review After Study Approval, Recordkeeping in Clinical Investigations, Recruiting Study Subjects, Payment To Research Subjects, Screening Tests Prior to Study Enrollment, A Guide to Informed Consent Documents, Informed Consent and the Clinical Investigator
May 9, 1997	International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline
UVA IRB website	http://www.healthsystem.virginia.edu/vprgs/irb/

REFERENCES TO OTHER APPLICABLE SOPs

All SOPs are applicable to this SOP

ATTACHMENTS

Attachment:	Form FDA 1572
Attachment:	Financial Disclosure by Clinical Investigators
Attachment:	Personnel and Delegation of Duties Form
Attachment:	Authorized Signature/Roles and Responsibilities Form
Attachment:	Responsibilities of the Investigator
Attachment:	Responsibilities of the Clinical Research Coordinator

PROCEDURES

• Principal Investigator • Sub-Investigator • Clinical Research Coordinator • Study Pharmacist • Support staff	1. Conduct each clinical study according to local, state and government (e.g. FDA) regulations and guidelines (and according to the policies and procedures of this institution)
	2. Ensure that the study team is informed in a timely manner of all study-related activities through meetings, the appropriate use of memos, e-mails, reports, etc.
	3. Ensure the safety and welfare of study subjects by being knowledgeable about ongoing study protocol and investigational article(s).
• Principal Investigator	4. Read and understand the IRB Investigator's Agreement to acknowledge the responsibilities of the principal investigator (found in IRB protocol).
	5. If applicable for the study, read, understand then sign Form FDA 1572 to acknowledge responsibilities of the principal investigator as defined by FDA regulations.
	6. If applicable, complete a financial disclosure form detailing all financial interests in the sponsoring company/organization.
	7. While retaining knowledge of, and overall authority for, the conduct of all studies, supervise members of the research team qualified by their education and training (and state and local laws) to accept the responsibilities for study-related activities not directly performed by the PI.
	8. Document the delegation of responsibilities (Refer to attachments: Personnel and Delegation of Duties Form or Authorized Signatures/Roles and Responsibilities Form).
	9. Participate as appropriate in the hiring and training of individuals recruited as members of the research team.
	10. Assign trained research coordinators to manage each clinical study (planned or ongoing).
	11. If the study is sponsored, ensure that specific sponsor requirements of the PI are fulfilled as requested.
	12. If applicable, meet with sponsors' representatives, as appropriate, to discuss planned and ongoing studies.

13. If applicable, meet with auditors (internal, IRB, sponsor, local, state and/or federal regulators) at the conclusion of their audits to review findings.

- Clinical Research Coordinator

14. Develop organizational aids and checklists to facilitate subject recruitment and enrollment as well as the collection of complete and accurate study data.

15. Enroll subjects and manage their participation according to ethical, regulatory, and protocol-specific requirements.

16. Maintain the regulatory files for each research project.

17. Participate in quality assurance activities (monitoring visits, internal audits, sponsor audits, local, state and/or federal audits).

- Research Team

18. Fulfill those job responsibilities specific to job title according to federal regulations and guidelines as well as the appropriate institutional SOPs.