TITLE: Responsibilities of The Study Team	
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Applicable Regulations & Guidelines:

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 record keeping 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
21 CFR 54	Financial Disclosure by Clinical Investigators
FDA Information Sheet January 1988	Guidelines for the Monitoring of Clinical Investigations
FDA Information Sheets October 1998	Frequently Asked Questions, Continuing Review After Study Approval, Recruiting Study Subjects, Payment to Research Subjects, Screening Tests Prior to Study Enrollment, A Guide to Informed Consent, Sponsor-Investigator-IRB Interrelationship
April 1996	International Conference on Harmonisation Good Clinical Practice: Consolidated Guideline (ICH-E6)

Other References: All SOPs are applicable to this SOP.
Delegation of Responsibility / Training Log (optional form)

Responsible Personnel: This SOP applies to those members of the clinical research team involved in supervising, managing, or conducting study-related activities. This includes the following:

- Principal investigator
- Sub investigator
- Research nurse/Study coordinator (CRA/CRC/clinical trials specialist)
- Regulatory Affairs Coordinator
- Project manager
- Study pharmacist
- Support staff

Policy Statement: The PI has the authority to delegate responsibility to individual members of the research team; however, the PI is ultimately responsible for the overall conduct of the study.

Procedure:

A. Administrative responsibilities

• PI • Research nurse/ Study coordinator • Regulatory Affairs Coordinator	Participate as appropriate in the hiring and training of individuals recruited as members of the research team. Assign trained research nurse/coordinators to manage each clinical study planned or ongoing at this site. Manage the business aspects of studies, including developing and negotiating study budgets and contracts. Design appropriate recruitment strategies and track study enrollment. Communicate with the IRB as appropriate.

B. General responsibilities of the research team

• PI • Sub investigator • Project manager • Research nurse/ Study coordinator • Study pharmacist • Support staff	Conduct clinical studies according to FDA regulations and guidelines and SOPs of this clinical site and according to the policies and procedures of the DF/HCC. Ensure that the PI is informed in a timely manner of all study-related activities through email notifications and meetings. Ensure the safety and welfare of study subjects by being knowledgeable about ongoing study protocols and investigational articles. All investigators and covered research personnel must comply with federal regulations governing disclosure of personal, professional or financial interests in a research study that may impact upon its conduct, evaluation or outcome.

C. Individual responsibilities within the research team

• PI	Sign Form FDA 1572 to acknowledge responsibilities as defined by the regulations. Provide sponsor with required information that either: Attests to the absence of financial interests or arrangements as described in the regulations (CFR 54.4) and reported on Form FDA 3454 that is completed by the sponsor, Or Provides the sponsor a complete and accurate disclosing of financial interests and arrangements as described in the regulations (CFR 54.4) and reported on Form FDA 3455 that is completed by the sponsor. 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 these responsibilities for study-related activities not directly performed by the PI. Document the delegation of responsibilities (See Delegation of Responsibility /Training Log). Ensure the safety and welfare of study subjects by being knowledgeable about ongoing study protocols and investigational articles. Participate as appropriate in the hiring and training of individuals recruited as members of the research team. Assign trained research nurse/coordinators to manage each clinical study planned or ongoing at this site. Ensure that specific sponsor requirements of the PI are fulfilled as requested. Meet with sponsors' representatives as appropriate to discuss planned and ongoing studies. Meet with auditors (internal, sponsor and FDA) at the conclusion of their audits to review findings.

• Research nurse/ Study coordinator • Project manager • Regulatory Affairs Coordinator	Develop organizational aids and checklists to facilitate patient recruitment and enrollment as well as the collection of complete and accurate study data. Enroll subjects in studies and manage their participation according to ethical, regulatory, and protocol-specific requirements. Maintain the regulatory and study files for each research project. Participate in quality assurance activities (monitoring visits, internal audits, sponsor audits, FDA audits).
• Research study team	Fulfill those job responsibilities specific to that job title according to federal regulations and guidelines as well as the appropriate SOPs.

NOTE: The Delegation of Responsibility / Training Log is a mandatory form provided to the study teams for use with investigational PI-initiated trials as a tool for managing the trial. This form is required for studies activated after 6/07/07.

Original Approval Date: CLINPOC 9/01/05
Revision Dates: CLINPOC 5/02/06, 5/08/07
Effective Date: 6/02/06, 6/08/07