TITLE: Responsibilities of the Research 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), section 4

Other References: All SOPs are applicable to this SOP.

Attachments: Delegation of Authority/Responsibility Log

Responsible Personnel: This SOP applies to those members of the research team involved in supervising, managing, or conducting study-related activities. This includes the following: Overall PI, Site PI, Co-investigator, Research Nurse/Study Coordinator, Regulatory Affairs Coordinator, Clinical Research/ Project Manager, Study Pharmacist

Policy Statement: The Overall Principal Investigator has the authority to delegate responsibility to individual members of the research team; however, he/she is ultimately responsible for the overall conduct of the study. A delegation of authority/responsibility log must be completed for each study with the key delegated tasks assigned to the appropriate person(s) involved in the study.

Background: The Delegation of Authority/Responsibility Log is a mandatory form for use with investigational agents. This form is required for investigational PI-initiated studies activated after 6/7/07.

Procedure:

A. Administrative responsibilities

• PI • Research nurse/ Study coordinator • Regulatory Affairs Coordinator	Ensure research team is qualified and trained to conduct trial related activities. 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 • Site PI • Co-investigator • Clinical Research/Project manager • Research nurse/ Study coordinator • Study pharmacist •	Conduct clinical studies according to FDA regulations and guidelines, and SOPs of this clinical site, and DF/HCC policies and procedures. 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 participants by being knowledgeable about ongoing study protocols and investigational agents. 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

• PI	Provides the sponsor a complete and accurate disclosing of financial interests and arrangements as described in the regulations and reported n Form FDA 3455 that is completed by the sponsor. Obtain the appropriate IRB approval for the clinical trial prior to beginning any research related activities. Adhere to the provisions of the investigational plan as outlined in the clinical trial protocol and modify study procedures only after receiving the appropriate approval from the study sponsor and/or the Institutional Review Board (IRB) unless otherwise required to maintain the immediate safety and welfare of participants. 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 Authority/Responsibility Log). Ensure the safety and welfare of study participants by being knowledgeable about ongoing study protocols and investigational products. Maintain adequate control of the investigational product including acquisition, distribution, and destruction as well as secure storage according to the provisions outlined in the study protocol, Investigator's Brochure, package insert, and/or the policies of the clinical site. This may be delegated to Pharmacy and/or an investigational pharmacist. Meet with sponsors' representatives as appropriate to discuss planned and ongoing studies. Meet with auditors (internal, sponsor and FDA) as needed and at the conclusion of their audits to review findings.

• Research nurse/ Study coordinator • Clinical Research/Project Manager • Regulatory Affairs Coordinator	Develop organizational aids and checklists, as applicable, 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).

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